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Supreme Court, U.S.
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In The
Supreme Court of the United States

NOVELTY, INC.,

Petitioner,

v.

MICHELLE M. LEONHART, IN HER OFFICIAL CAPACITY AS DEPUTY ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION; THE U.S. DRUG ENFORCEMENT ADMINISTRATION; THE U.S. DEPARTMENT OF JUSTICE; AND THE UNITED STATES OF AMERICA,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

This case involves a D.C. Circuit decision that upholds DEA revocation of a DEA List 1 chemical registration despite a three way conflict that left the court without a majority rationale for decision. Judge Henderson ruled that the DEA properly interpreted "principal place of business" in 21 U.S.C. § 822(e) to require registration of over 100 cross-docking stations used in-transit during shipment of product from the registrant's headquarters to its retail customers. Judges Tatel (concurring) and Brown (dissenting) reasoned that the DEA interpretation was contrary to the statute's plain meaning, but Tatel nevertheless ruled that dicta in the DEA decision questioning whether cross-docks were safe justified a *post hoc* appellate conclusion that the cross-docks were unsafe (an internally inconsistent ruling because Tatel expected security akin to registered facilities for cross-docking stations he agreed did not need to be registered). Thus, the case rests on no rationale for decision acceptable to a majority and should not have resulted in an affirmance. The case thus presents the following questions:

(1) Whether the decision below effectively vests in the Drug Enforcement Administration (DEA) discretionary authority beyond the limits of the Controlled Substances Act (CSA), 21 U.S.C. § 823(h), such that the Deputy Administrator (DA) may revoke the registration of any DEA registrant on almost any

QUESTIONS PRESENTED – Continued

pretext without effective federal judicial review under the CSA or the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(b), in contravention of the decisions of this Court, of the sister circuits, and of the D.C. Circuit.

(2) Whether the decision below is incompetent due to contradictory bases for decision, because no two judges on the panel agreed on a single basis for DEA registration revocation (and the basis articulated by one judge in the majority contradicts the basis articulated by the other).

(3) Whether the decision below upholds the DA's DEA registration revocation based on an impermissible *post hoc* rationalization in contravention of this Court's precedent, that of the D.C. Circuit, and that of all sister circuits, wherein reliance on the court's own *post hoc* rationalization as a substitute for the agency's actual basis for decision is forbidden.

PARTIES TO THE PROCEEDING

All of the parties are listed in the caption of the Petition.

CORPORATE DISCLOSURE STATEMENT

Petitioner Novelty, Inc. ("Novelty"), by counsel and pursuant to Sup. Ct. R. 29(6), states that it has no parent companies. No publicly-held company has any ownership interest in Novelty. Novelty is a distributor of novelty items and other goods sold to convenience stores throughout the United States, including, but not limited to, over-the-counter cold and cough products containing List 1 chemicals under the Controlled Substances Act.

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The D.C. Circuit issued its decision on June 22, 2009, reported at *Novelty, Inc. v. DEA,* 571 F.3d 1176 (D.C. Cir. June 22, 2009) ("D.C. Circuit Decision") (App. 1). That Court's unpublished order denying rehearing, *Novelty, Inc., v. DEA*, No. 08-1296 (D.C. Cir. Filed July 28, 2009) (App. 365), issued on July 28, 2009. The DA's Final Order revoking Novelty's DEA registration issued on September 10, 2009, reported at *Novelty Distributors, Inc.; Revocation of Registration*, 73 FR 52689 (September 10, 2008) ("Order") (App. 59). Administrative Law Judge Gail A. Randall (ALJ) rendered her ruling in favor of Novelty's continued registration on May 21, 2008. *See In Re Novelty Distributors*, DEA Dkt. No. 08-33, Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (May 21, 2008) ("ALJ Decision") (App. 137).

JURISDICTION

The D.C. Circuit entered its decision on June 22, 2009 and denied Novelty's timely Petition for Rehearing and Suggestion for Rehearing En Banc on July 28, 2009. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS

The statutes and regulations involved in this case are presented verbatim in the statutory addendum (Sup. Ct. R. 14(f), (i)(v)).

STATEMENT OF THE CASE

This Petition raises questions of great importance for all DEA registered distributors of schedule listed chemicals (SLCs). From 2004 until September 2008, the DA issued 54 consecutive decisions revoking or refusing to grant registrations for independent distributors (Independents) that sell ephedrine and pseudoephedrine cough and cold remedies to retail stores in direct competition with the distributors of Wyeth's Primatene and Primatene Mist and Pfizer's Sudafed. Every company the DA charged she condemned, revoking or denying 54 out of the 54 registrations she called into question.[1] She has done so even in instances where there is no reliable evidence of diversion to the illicit methamphetamine trade, as in Novelty's case. Despite state criminal actions against over 20 distributors of the Wyeth and Pfizer brands to pharmacies, the DA has not brought

[1] Since the Novelty case was decided below, the DA granted a single renewal of application on July 24, 2009. *See CBS Wholesale Distributors*, 74 FR 36746 (2009).

any action against them.[2] Hers has been a biased, anticompetitive campaign where in the case of Independents a record void of criminal conduct is treated equally with one replete with it and where a charge from the DA leads to her ultimate decision to revoke regardless of the evidence adduced at hearing – with the rights of the accused suspended throughout. That biased, anticompetitive campaign the majority D.C. Circuit decision condones in perpetuity unless and until this Court intervenes to restore the rule of law.

By resolving the issues presented here, this Court will decide whether the DA may wield her power arbitrarily and capriciously beyond statutory limits by revoking the DEA registration of a company that directs its products to those with legitimate

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[2] In an illegitimate line of cases preceding Novelty's, the DA, in reliance on the very "expert" rejected in the Novelty case, Jonathan E. Robbin, proclaimed there to be two markets for ephedrine and pseudoephedrine. One, said to be legitimate, was the "traditional market" served by the distributors of the Pfizer and Wyeth brands that Robbin presumed, despite contrary evidence, free from diversion risk (the pharmacies). Another was termed the "nontraditional market" served by independent distributors and competitors to the Pfizer and Wyeth brands that Robbin presumed inherently at risk of diversion (convenience stores). There is no sound evidence to support this distinction, yet, the DA has credited it since 2004 and has revoked or denied at least 54 DEA registrations in reliance upon it. *See, e.g., Sunny Wholesale, Inc.*, 73 FR 57655, 57666-67 (2008); *Wholesale, Inc.*, 72 FR 71956 (2007); *Tri-County Bait Distributors*, 71 FR 52160, 52161-62 (2006); *Joy's Ideas*, 70 FR 33195, 33199 (2005); *Branex, Inc.*, 69 FR 8682, 8690-92 (2004).

medical need without requisite proof that the company's principals engaged in any unlawful activity or created any provable risk of diversion to the illicit methamphetamine trade.

This case proved to the ALJ's (and to Circuit Judge Janice Brown's) satisfaction, based on Emory University expert statistician Joanna M. Shepherd, Ph.D.'s rebuttal testimony, that the DEA's sole "expert" on diversion risk was inexpert in statistics (had no Ph.D. in that or any other subject) and was biased. That same person, Jonathan E. Robbin, the DA used in at least 26 cases to justify revocation, often on the basis of Robbin's contrived (and patently absurd) representation (also made in Novelty's case) that the sale of any SLC cough and cold products by a single convenience store over $14.39 per month was proof of sales beyond legitimate demand. On a complete record, the ALJ concluded that Robbin lacked credibility, relied on an impeached methodology (one that violated basic principles of statistics), and employed biased data.[3] Novelty not only refuted Robbin, it proved to the DEA ALJ's satisfaction that Novelty posed no unreasonable risk of diversion; had a long history of compliance with the

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[3] Even after accepting the ALJ's findings on Robbin's incompetence and bias in the Order, the DA continues to rely on Robbin's figures as the basis for the national ephedrine and pseudoephedrine quota. *See Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2009*, 74 FR 32954.

law (indeed, no executive of the company had ever been accused of a criminal offense); had developed a sophisticated anti-diversion program exceeding federal regulatory requirements; had never been complicit in drug diversion; and had proven itself a reliable partner for DEA.

Despite that proof, the DA reversed the ALJ's well-reasoned decision and condemned Novelty anew on grounds not recited in her charges against the company and not the subject of the evidentiary hearing before the DEA – grounds two D.C. Circuit Judges rejected. Nevertheless, relying on different (and contradictory) *post hoc* rationales, two of the D.C. Circuit Judges upheld the DA's decision, ending the employment of 26 Novelty employees and forcing an $8,000 per year reduction in income for 100 more, not to mention the loss of major contracts with Novelty's primary customers.

In her dissent from the decision, Judge Brown lamented:

> It does not matter that no Novelty executive has ever been convicted of a crime. It does not matter that notwithstanding Novelty's millions of sales, the best evidence the DA can point to of diversion is one – *one!* – instance from over six years ago. It does not matter that the DEA inspected Novelty's records for years and never peeped about a problem before deciding to bring down the full weight of the Executive Branch on Novelty's head. It also is irrelevant that

> Novelty has credibly offered to overhaul its internal processes to comply with the DA's whims.

D.C. Circuit Decision at 1199 (Brown, J., dissenting); App. 57-58.

Judges Henderson and Tatel offered separate and conflicting bases for the decision. There is no majority basis for violation. Judge Henderson found Novelty violated the CSA, 21 U.S.C. § 822(e), presuming each in-transit cross-docking station used by Novelty truck transport to be a "principal place of business" that had to be DEA-registered under Section 822(e). She then justified revocation because of isolated single instances of alleged violation of Novelty's own corporate policy,[4] not required by federal law, that distributors limit sale of 24 count SLC packages to two per transaction[5] and because of record-keeping errors that amounted to less than 0.00012% out of millions of properly recorded transactions.[6] Judge

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[4] The dissent correctly explained an error rate of no more than 0.2%. *See D.C. Circuit Decision* at 1197 (Brown, J., dissenting).

[5] Faulting Novelty for its convenience store customers' rare violation of Novelty's 24 count SLC package sales limit makes little sense for a second reason. Under federal law, Novelty is forbidden to review the content of those customers' sales logs. Only DEA may examine the logs. *See D.C. Circuit Decision* at 1195 n.6 (Brown, J., dissenting) (citing Order at 52699 n.43); App. 48. Consequently, the isolated instances of violation found by DEA could not have been discovered by Novelty.

[6] *See* ALJ Decision at 78; App. 259 (discussing very low error rate of 60,000 out of 300-500 million units).

Tatel rejected Judge Henderson's grounds, finding no DEA registration required under Section 822(e) for in-transit cross-docking stations, interpreting "principal place of business" within the CSA not to reach every point in-transit between a company's headquarters and the ultimate delivery point. Rather, Judge Tatel upheld the DA because by concluding (on a record void of evidence) that security at the cross-docking stations (the very ones he said were not required to be registered and thus not required to have the security of a registered facility) was "unlikely" to meet the security requirements of registered facilities. Thus, Judge Tatel's position contradicts itself while also contradicting Henderson. He also concluded that the few instances of convenience store violation of Novelty's 24 count package sales limit (a limit not required by federal law) justified the sanction of revocation. Accordingly, the D.C. Circuit decision is incompetent because the basis articulated by one judge in the majority contradicts the basis articulated by the other.

The D.C. Circuit's decision conflicts with precedent from this Court, the D.C. Circuit, and the sister circuits. It substitutes the panel's own *post hoc* rationale for decision for the DA's articulated basis. Had the case been evaluated on the DA's basis, two of the three panel judges by their own statements would have reversed. Instead, upon a new rationale for revocation, two of the three upheld registration revocation. The decision tells the DA that the D.C. Circuit will uphold her decisions even when the

rationale she articulates fails to support the decision she reaches. To arrest and reverse the lawless actions, Novelty respectfully requests grant of this Petition.

A. Novelty, Inc.

Under the Controlled Substances Act ("CSA"), "[e]very person who . . . distributes any . . . list I chemical shall obtain annually a registration issued by the Attorney General." 21 U.S.C. § 822(a)(1). The Attorney General must register all applicants unless he determines registration to be "inconsistent with the public interest." 21 U.S.C. § 823(h). He must evaluate five factors in determining whether the public interest would be disserved by registration:

> (1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
>
> (2) compliance by the applicant with applicable Federal, State, and local law;
>
> (3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
>
> (4) any past experience of the applicant in the manufacture and distribution of chemicals; and
>
> (5) such other factors as are relevant to and consistent with the public health and safety.

21 U.S.C. § 823(h).

Between 1998 and 2007, DEA never issued Novelty a warning letter, never accused Novelty of committing any rule violation, never informed Novelty that its product was illegally diverted,[7] and never told Novelty that it acted in any way inconsistent with the public interest. DEA conducted 3 investigations of Novelty, informing Novelty after each that it was in full compliance with DEA requirements and issuing Novelty registration renewals.[8] The record abundantly supports the DEA ALJ's conclusion that Novelty's executives were law-abiding, credible, dedicated to the institution and maintenance of diversion controls, and deserved the agency's trust.[9]

Novelty expended millions on diversion risk reduction training, education, security, and monitoring. Novelty distributed its products through a

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[7] *See D.C. Circuit Decision*, at 1195 (Brown, J., dissenting) ("The best the DA can muster is an event from 2002 when 'twenty-two' [bottles of ephedrine based product] were found at an illicit methamphetamine laboratory . . . and it is uncertain whether [Novelty] even distributed them"); App. 47.

[8] *See Novelty, Inc. v. Tandy et al.*, No. 1:04-cv-01502 (S.D. Ind. 2008) (Hamilton, C.J.) ("The DEA conducted investigations of Novelty in 2002-2003 and in 2007 . . . , and the DEA continued to be aware of Novelty's distribution practices. At no time during the pre-registration or subsequent investigations did the DEA inform Novelty that its practices violated . . . federal regulations regarding distribution of List I chemicals"), *available at*, 2008 WL 3835655 ("Hamilton Opinion"); App. 373-374.

[9] *See, e.g.*, ALJ Decision, at 98-99 (summarizing Novelty's compliance with the CSA); App. 279-281.

costly closed system of distribution employing Novelty manned trucks, manned by Novelty anti-diversion trained drivers. Novelty products were shipped from its headquarters over great distances for temporary placement in padlocked cross-dock storage units where they were transferred, usually within hours, to regional Novelty route sales persons' ("RSPs") trucks for convenience store delivery. These RSPs then directly stocked the SLCs in Novelty-supplied, locked plexiglass cabinets serviced by Novelty employees. Novelty did not employ middlemen.

Novelty employed multiple, complimentary, and effective means to identify and eliminate diversion risk, resulting in no documented instance of diversion despite over 300-500 million transactions of SLCs. *See* ALJ Decision at 78; App. 250. Novelty imposed limits on customer purchases not required by law, such as its 24 count package sales limit.[10] Novelty sold only to DEA self-certified customers whose employees completed Novelty's anti-diversion course and agreed to abide by Novelty's sales limits. Novelty voluntarily reduced ephedrine content in its private label 24 count product from 25 mg to 12.5 mg to help

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[10] Novelty's case limit on sale of 24 count ephedrine packets was honored by almost all of its distributors; the evidentiary record reveals that only a fraction of one percent were shown by the government not to have abided by the limit and even then no diversion was found. *See D.C. Circuit Decision* at 1197 (Brown, J., dissenting) ("the error rate thus may have been less than .2%"); App. 52.

reduce diversion risk. *See* ALJ Decision at 60; App. 225. In addition, Novelty packed its SLCs in sealed, tamper resistant containers. Novelty employed a state of the art, handheld computer system for every Novelty driver to log and communicate to Novelty headquarters up to date SLC inventory and sales data.

In May 2004, DEA Diversion Group Supervisor Dan Raber sent an advisory letter to all independent distributors of ephedrine and pseudoephedrine SLCs ("Raber letter").[11] There is no evidence that the letter was sent to Pfizer or Wyeth brand distributors. The Raber letter stated a position at odds with prior DEA policy: that overnight List I chemical storage in delivery trucks on long routes would be permissible only if the products had been preordered; the sales representative was a company employee; the delivery vehicle was company owned; and that representative stayed overnight at a hotel. *See Raber Letter* at 1; App. 413-415.[12] Alternatively, the Raber letter stated that registrants could use overnight mail carriers (FedEx, UPS, and USPS). Novelty believed its system more secure than those stated in the Raber letter. Moreover, the letter appeared to impose an unlawful

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[11] *See* Raber Letter at 1; App. 413-415.

[12] In her dissent Judge Brown found the Raber letter distinctions mind-boggling: "I am confused, however, about the logic in the Raber Letter . . . [W]hy does it matter if the drugs are for 'pre-placed customer specific orders' or for on-site orders?" *D.C. Circuit Decision* at 1196 n.7 (Brown, J., dissenting); App. 48.

agency rule adopted without requisite notice and comment rulemaking. Novelty filed suit seeking declaratory and injunctive relief in *Novelty, Inc. v. Tandy et al.*, No. 1:04-cv-01502 (S.D. Ind. 2008) (Hamilton, C.J.) *available at*, 2008 WL 3835655 ("Hamilton Opinion"); App. 369. During the pendency of its suit, Novelty pledged to change its shipping model if the DA, upon a review of the facts, adopted the Raber letter or another requirement.[13] Thus, Novelty did not evince an intent to violate the law. Rather, it sought clear judicial or administrative guidance as to the legality of the Raber letter and whether its content constituted a binding rule. The DA never revealed whether she endorsed the Raber letter until her final decision against Novelty, over four years after the letter's date. District Court Judge Hamilton determined that the letter was not an agency rule (a decision he described as a close call) and, thus, dismissed Novelty's suit. *See Hamilton Opinion* at 35-36; App. 388-389. Although Novelty's suit concerning the legality of the Raber letter and pledge to the DA to follow any requirement she wished to impose were proof of Novelty's good faith, the DA construed Novelty's suit as evidence of Novelty's non-compliance with the law. She did so

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[13] *See* ALJ Decision at 19 ("Mr. Bledsoe credibly testified that, should the DEA's final order instruct the Respondent to change its shipping methods or DEA registrations, the Respondent would comply with such directions"); App. 165; *see also D.C. Circuit Decision* at 1196 (Brown, J., dissenting) ("Novelty credibly offered to modify its distribution network to address safety concerns"); App. 49.

disingenuously because DEA represented to the federal district court in Indiana that the Raber letter was not a binding agency rule. Thus, the DA avoided Judge Hamilton's review on the basis that the letter was not binding yet thereafter declared the letter binding in her Order (and Novelty a law violator for not following it). That legerdemain reinforces the conclusion that the DA wields unbridled discretion beyond statutory limits.

In 2007, Novelty filed comments challenging a DEA decision to set quota limits on ephedrine, pseudoephedrine, and phenylpropanolamine below legitimate demand in the market.[14] In those comments and in a suit it brought after adoption of the below market demand limits, Novelty filed suit in federal court challenging the biased statistics generated by none other than Jonathan E. Robbin, the same "expert" held incompetent and biased by the DEA ALJ in Novelty's case.[15] Shortly after Novelty's

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[14] *See Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2008*, 72 FR 73361.

[15] *See, e.g., Novelty v. DEA*, No. 08-1026 (D.C. Cir.) (Petition for review of DEA's Annual Assessment of Needs ("AAN") for ephedrine, pseudoephedrine, and phenylpropanolamine). DEA calculated its Annual Assessment of Needs for ephedrine products using, in part, the statistical analysis of Jonathan E. Robbin. In *Novelty v. DEA*, No. 08-1026, Novelty sought to challenge Robbin's opinion and his concept of a "traditional market." Following the ALJ hearing in the instant action, the ALJ determined that Robbin's statistical analysis was not credible. *See* ALJ Decision at 94-98; *see also Novelty, Inc.*, 571

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suit, DEA issued its Order to Show Cause (OSC) against Novelty.

B. DEA

On January 17, 2008, DEA issued an OSC to Novelty, soliciting Novelty's response as to why DEA ought not summarily revoke Novelty's registration.[16] In anticipation of the OSC, the DA dispatched agents to investigate Novelty. The ALJ and Judge Brown admonished DEA for investigative irregularities, including imposition of a prior restraint on Novelty's right to record investigative irregularities taking place at Novelty's headquarters.[17] *See D.C. Circuit Decision*, at 1192 n.3 (Brown, J., dissenting) ("such tactics do not reflect well on the United States"); App. 38. The OSC included six allegations – the DA's foundation for presuming Novelty's continued registration an imminent threat to the public under

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F.3d at 1192 n.3 (Brown, J., dissenting) ("[o]ne wonders if the DEA feels remorse for preying on companies that lack the wherewithal or sophistication to fight back against sloppy statistics"); App. 41.

[16] *See* OSC at 1; App. 417-421.

[17] *See D.C. Circuit Decision*, at 1192 n.3 (Brown, J., dissenting) (stating "Agents interfered with Novelty's understandable efforts to document in real time the search of the company's own facility by forbidding the use of and disabling video and audio recorders." These agents also "requested 12,000 additional pages of documents," giving only "three hours to produce them," and threatened an executive with arrest [a threat the agents had no lawful authority to make or effectuate]); App. 38.

the factors in 21 U.S.C. § 823(h).[18] Following an exhaustive two week hearing, each was held unsupported, demonstrably without merit, or insufficient to support revocation by the ALJ.[19] In her Order, the DA acknowledged a total lack of evidentiary support for all but one of her charges. The DA relied instead on new, alternative bases for revocation not the subject of the hearing.[20] *D.C. Circuit Decision,* at 1192 (Brown, J., dissenting); App. 40-41.

The ALJ found the charge of diversion of Novelty-distributed product unproved because the product in question was never shown to have actually been distributed by Novelty. Repeatedly DEA agents told Novelty that its product had never been found in the illicit trade. *See* ALJ Decision at 13-14, 74; App. 157-159, 245-246; *see also* OSC Hearing Transcript at 1099-1102 (DEA Diversion Investigator Madeline Kuzma testifying that DEA never gave Novelty a notice of diversion); App. 429-431. The ALJ

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[18] *See id.* at 1191; App. 37-38.

[19] *See* ALJ Decision at 37-39 (Novelty did not distribute products in forms or packages that violated law); App. 190-193; *id.* at 87-88 (60,000 dosage units were not unaccounted for; the DEA audit was insufficient); App. 263-266; *id.* at 91 (Novelty did not distribute to stores that were not self-certified); App. 269-270; *id.* at 96-97 (DEA "expert" witness Robbin was inaccurate and unreliable, and DEA failed to prove excessive sales); App. 276-279.

[20] *See D.C. Circuit Decision,* at 1192 (Brown, J., dissenting) (citing Order at 52695-97 (finding unsubstantiated several allegations in the OSC); App. 40-41.

additionally found DEA's audit of Novelty inventory[21] incompetent and that DEA lacked a reasonable basis to estimate legitimate SLC demand.[22] The ALJ found Novelty officials honest and credible in their willingness to ensure that Novelty's system met DEA requirements.[23] The ALJ credited Novelty with a "history of compliance." ALJ Decision at 100-101; App. 281-283. She held the public interest best served by continuing Novelty's DEA registration with conditions. *See id.* ("I conclude that this is a case where teamwork between the DEA and this major distributor would further . . . the public interest . . . I recommend that the [DA] not revoke this . . . registration").

In her Order rejecting the ALJ's recommendation, the DA ruled that (1) Novelty did not maintain effective controls against diversion as a result of inadequate recordkeeping and distribution to some stores in excess of Novelty's average customer purchase amounts and (2) Novelty violated 21 U.S.C. § 822(e) by not registering each in-transit cross-dock.[24] Her decision rests on no proof of actual diversion to the illicit methamphetamine trade. It rests on the assumption that Novelty's system of distribution, the very same DEA upheld without

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[21] *See* ALJ Decision at 87-88; App. 190-193.

[22] *Id.* at 96-97; App. 276-279.

[23] *Id.* at 98-99; App. 279-281.

[24] *See* Order at 52691 (summarizing reasons for revocation); App. 66-71.

question in every annual registration renewal since 1998, created an unacceptable diversion risk.

The DA determined that in-transit locations where SLCs are temporarily stored must be registered as "principal places of business" under 21 U.S.C. § 822(e) and held Novelty violated that "rule," the legally binding status of that rule she first announced in her Order. She construed three of four Section 823(h) factors as favoring revocation based entirely on that single legal statutory interpretation, an interpretation rejected by two D.C. Circuit judges.[25] *See* Order at 52702; App. 125-126.

Section 822(e) provides that a distributor of List I chemicals must obtain "a separate registration . . . at each principal place of business . . . where the applicant . . . distributes . . . list I chemicals." 21 U.S.C. § 822(e). In her Order the DA found each of Novelty's over 100 in-transit cross-docks "principal places of business." *See* Order at 52700-52702; App. 116-125.

The DA also construed Novelty's correspondence concerning possible reliance on a statutory exception

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[25] *See* Order at 52698-52702 (citing use of the unregistered cross-dock storage sheds in her analysis under 21 U.S.C. § 823(h)(1), (2), and (4)); App. 104-127; *but see D.C. Circuit Decision* at 1187-1188 (Tatel, D., concurring in part) (holding the DA's interpretation of 822(e) invalid under *Chevron*); App. 27-31; *id.* at 1193-1195 (Brown, J., dissenting) (holding the DA's interpretation of 822(e) invalid under *Chevron*); App. 42-47.

for SLC sales agents under 21 U.S.C. § 822(c)(1) proof that Novelty could not be trusted to distribute SLCs. The record revealed that Novelty never effectuated any plan to become a sales agent and merely broached the subject via the letter. *See D.C. Circuit Decision* at 1197-1198; App. 53-55.

C. The D.C. Circuit Decision and Issues Presented

Novelty challenged the DA's Order as a violation of the Administrative Procedure Act, 21 U.S.C. § 822(e); 21 U.S.C. § 823(h). The D.C. Circuit's per curiam decision upheld revocation with two "splintered-on-seemingly-all-points-but-outcome" concurring statements from Judges Henderson and Tatel and a vigorous dissent from Judge Brown. *D.C. Circuit Decision* at 1199; App. 56.

In her dissent, Judge Brown found six fatal errors in the Order requiring reversal and remand. She found almost every original DA allegation against Novelty without merit. *Id.* at 1192-1193; App. 40-42. She condemned the DA's interpretation of Section 822(e), it having written the word "principal" out of the statute. *Id.* at 1193-1195 (labeling the DA's interpretation "Hogwash"); App. 42-47; *see also id.* ("[t]he heart of the DA's analysis – that unregistered storage units *always* violate federal law – contradicts the statute"); App. 42-43. She found the DA's "expert" incompetent and the DA to have proceeded without evidence, logic, or statistics when she declared

Novelty's national average sales figure for SLCs to be the divining point of "legitimate demand." *See id.* Judge Brown found that the DA had erected a "zero-tolerance standard" in violation of the statute by not allowing the slightest mistake in business operations. *Id.* at 1197 (" . . . no complex system can be 100% foolproof " and "the DA applied an unreasonable zero-tolerance standard that Congress . . . did not intend"); App. 52. The DA had rejected the ALJ's credibility findings summarily jumping to revocation without seriously considering whether registration conditions would suffice. *See id.* at 1196 ("DA wrongfully rejected the ALJ's credibility findings based on her erroneous belief that the storage units were illegal"); App. 49.

Although Judge Tatel was "troubled by several aspects" of the DA's decision, he upheld it based on the DA's non-specific reference in dicta to security issues at certain of Novelty's cross-docks. *See D.C. Circuit Decision* at 1188-1190 (Tatel, D., concurring) (citing Order at 52698); App. 28-30. Judge Tatel credited the DA with making a finding of fact concerning the security of the cross-docks when she wrote in passim (absent specific evidence) that it was "unlikely" the units would meet DEA security requirements. *Id.* at 1188; App. 31. The security of Novelty's cross-dock storage units was not in issue in the OSC or at hearing. As a result, Judge Tatel's transformation of this dicta into a decisional reliance was a *post hoc* rationalization in conflict with this Court's, the sister circuits', and the D.C. Circuit's precedent.

Judge Henderson chose to uphold the DA's Order on grounds different from Judge Tatel. Henderson upheld the DA's erroneous interpretation of 21 U.S.C. § 822(e). *Id.* at 1184 (Henderson, K., concurring); App. 21; *but see id.* at 1187-1188 (Tatel, D., concurring) (holding the DA's interpretation of Section 822(e) invalid under *Chevron U.S.A., Inc. v. Natural Resources Defense Council,* 467 U.S. 837 (1984)); App. 27-31; *id.* at 1193-1195 (Brown, J., dissenting) (holding the DA's interpretation of Section 822(e) invalid under *Chevron*); App. 42-47.

REASONS FOR GRANTING THE PETITION

A. THE DA VIOLATED CSA LIMITS, 21 U.S.C. § 823(h), REVOKING A REGISTRATION ON A PRETEXT NOT COGNIZABLE UNDER THE STATUTE, WITHOUT EFFECTIVE FEDERAL JUDICIAL REVIEW UNDER THE CSA OR THE APA, 5 U.S.C. § 706(2)(b), IN CONTRAVENTION OF THE DECISIONS OF THIS COURT, THE SISTER CIRCUITS, AND THE D.C. CIRCUIT

The decision below condones the exercise of DA discretion beyond CSA limits, 21 U.S.C. § 823(h), upholding revocation on a pretext, without subjecting the DA's decision to effective federal judicial review under the CSA or the APA, 5 U.S.C. § 706(2)(b), in violation of this Court's, the sister circuits', and the D.C. Circuit's precedent.

This Court has required agencies to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 2866 (1983) (quoting *Burlington Truck Lines, Inc. v. U.S.*, 371 U.S. 156, 168, 83 S.Ct. 239 (1962)); *see also FCC v. Fox TV Stations, Inc.*, 129 S.Ct. 1800, 1810 (2009) (". . . we insist that an agency examine the relevant data and articulate a satisfactory explanation for its action") (internal citations omitted). An agency action is

> arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

State Farm, 463 U.S. at 43. Judicial review of an agency action is not just a formal process to "rubber-stamp [an] agency decision." *American Radio Relay League, Inc. v. FCC,* 617 F.2d 875, 879 (D.C. Cir. 1979); *see also Nat'l Wildlife Fedn. v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 924 (9th Cir. 2008) (requiring a court to engage in a careful, searching review to ensure that the agency has made a rational analysis and decision on the record before it). The

court must determine whether the decision was "based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Oreg. Natural Res. Council*, 490 U.S. 360, 378, 109 S.Ct. 1851 (1989) (internal quotation marks omitted).

In its decision the D.C. Circuit sanctioned the DEA's arbitrary and capricious decision by upholding revocation. The DA erroneously interpreted the controlling statute (which calls for reduction but not elimination of diversion risk, the latter possible only through a total ban on SLCs that Congress rejected). She imposed zero risk tolerance in violation of the CSA's plain and intended meaning. She invented an unreasonable litmus test (average Novelty sales) to adduce illegitimate market demand. She arbitrarily shifted the burden of proof to Novelty in violation of 21 C.F.R. 1309.54(b). Those actions violate the APA yet were condoned by the Circuit decision. As Judge Brown stated in dissent, the rule of law demands consistency, evenhandedness and predictability from an impartial adjudicator. Containing none of those requisites, the DA's decision is an abuse of power.

1. The DA's Zero Risk Standard Violates the CSA and the APA

Congress could have banned ephedrine and pseudoephedrine containing cough and cold remedies, thus creating a zero risk tolerance; instead, Congress

chose to protect the availability of ephedrine and pseudoephedrine for legitimate "medical, scientific, and industrial" uses. 21 U.S.C. § 823(b)(1). In condemning Novelty, the DA possessed neither evidence proving Novelty complicit in diversion nor evidence that Novelty executives were law violators. Each of her OSC charges were disproven. Presented with a record that did not support revocation, she nonetheless ordered it by relying not on her original charges but by reaching anew beyond those charges and the limits in 21 U.S.C. § 823(h).

The zero-risk standard she employed is precisely that kind of action inconsistent with statutory mandate that cries out for effective federal judicial review. When the DA revokes a registration under Section 823 based on any perceived transgression (such as those present here that have no meaningful link to diversion or other illegality), the system designed by Congress to provide for legitimate demand becomes rent, providing no meaningful weighing of factors and making revocation an ineluctable conclusion for every party the DA charges. Such a system is a sham and is tyrannical. Because the DA can revoke based on any error (even on one error out of millions of correct records maintained) without proof of a nexus to diversion, a registrant remains so at the DA's whim and caprice. If she brings charges, then it is a fait accompli that the registrant will lose its registration. The ALJ well understood the DA's

unlawful strategy bravely faulting her boss as follows:

> The DEA . . . seems to be trying to remedy [the meth] problem by restricting or eliminating the availability of such over-the-counter products by removing the distributors of SLC products to convenience stores from the market place. This action is based upon the premise that distributors are placing excessive amounts of SLC products into the market place by selling such products to their convenience store customers. Further, the DEA's premise also seems to be that these excessive amounts are being diverted to the illicit manufacture of methamphetamine. This record, however, calls such an analysis into question.

See ALJ Decision at 93; App. 273.

Judge Brown likewise appreciated that far from weighing statutory factors judiciously, the DA concluded her case at the time she brought her charges (her combined status as law maker, prosecutor, and judge thus destroys the separation of functions and gives her tyrannical power). *D.C. Circuit Decision* at 1199 (Brown, J., dissenting); App. 57-58.[26] DEA

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[26] Judge Brown cited various abuses in this case, including the refusal to allow Novelty to make a contemporaneous record of DEA's execution of a warrant on Novelty's premises. None was substantively addressed by the concurring Panel members. *See D.C. Circuit Decision* at 1191 n.2 (Brown, J., dissenting) (stating

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admits Congress did not intend to ban OTC ephedrine in retail stores,[27] the only way to achieve zero risk.[28] Demanding zero risk, the DA looks (and inevitably finds) some infraction, regardless of how innocuous and unconnected with diversion, and then deems that alleged infraction enough to support revocation without requisite proof of gravity. As Judge Brown explained, "[j]ust as 'safe' does not mean 'risk-free' 'maintenance by the applicant of effective controls against diversion' as used in 21 U.S.C. § 823(h) cannot mean perfect controls, an impossible standard." *See D.C. Circuit Decision* at 1197 n.9 (Brown, J., dissenting) (quoting *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 642, 100 S.Ct. 2844 (1980) (Stevens, J., plurality)); App. 52. With perfect compliance her required standard, the DA may scour Novelty's decade of compliance for an apparent blemish and then lay waste to Novelty's

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that "[s]uch tactics do not reflect well on the United States"); App. 38.

[27] *See, e.g., Implementation of the Comprehensive Methamphetamine Control Act of 1996*, 62 FR 52253 (Oct. 7, 1997) ("Congress [intended] that public access to the products at the retail level be protected . . . "); *see also PDK Laboratories, Inc. v. DEA*, 362 F.3d 786, 797 (D.C. Cir. 2004) ("no one doubts that Congress did not intend to ban, or give the DEA authority to ban, all sales of ephedrine-containing drugs in retail stores").

[28] *See D.C. Circuit Decision* at 1197 (Brown, J., dissenting) ("[i]gnoring that no complex system can be 100% foolproof, the DA applied an unreasonable zero-tolerance standard that Congress surely did not intend"); App. 52.

business on the basis of that de minimis imperfection without proof of any nexus to diversion.

Section 823(h) may not be construed to defeat satisfaction of legitimate demand. The statute contemplates an evaluative process (a weighing of Section 823 factors under the public interest, a flexible approach, not an inflexible one that compels revocation on the finding of any perceived error no matter how slight). That type of limitless power to condemn cannot be allowed to stand in any country that respects the rule of law. *See* BLACK'S LAW DICTIONARY 100 (7th ed. 1999) (defining "arbitrary" as "founded on prejudice or preference rather than on reason or fact").

2. The DA Invented an Unreasonable Test Based on Unreliable Data to Determine Market Demand for SLCs

Agency decisions based on data that is "unreliable or inadequately explained" are arbitrary and capricious and must be overturned. *Friends of the Boundary Waters Wilderness v. Bosworth*, 437 F.3d 815, 824 (8th Cir. 2006); *see also State Farm*, 463 U.S. at 43. Under 21 U.S.C. § 823(h), the DA found that Novelty sales amounted to a risk of diversion based not on any proof of diversion or of sales exceeding the legal limit, but on Novelty selling amounts above its own national sales average to some of its retail customers. *See* Order at 52699; App. 112-115. Without any empirical basis to conclude that a particular

quantitative amount sold necessarily leads to diversion (a grossly illogical assumption), the DA held Novelty's national sales average the arbitrary point above which illegitimate demand existed. The DA provided no reasoned analysis for that determination,[29] no market data, no multivariate statistical study. *See D.C.* Circuit Decision at 1196 (Brown, J., dissenting); App. 50. On that flawed assumption, she found the first factor of Section 823(h) "*strongly supports* the conclusion that [Novelty's] registration 'is inconsistent with the public interest.'" Order at 52700 (emphasis added); App. 115-116.

To a mind possessed of a modicum of mathematical sensibility, a national sales average says nothing about legitimate demand, "after all, 50% of all convenience stores should be expected to have sales greater than the average." *D.C. Circuit Decision* at 1196 (Brown, J., dissenting); App. 50-51. The DA's reliance illogically assumes similarity across the

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[29] The DEA originally relied upon the supposed expert Jonathan Robbin to determine legitimate market demand for ephedrine/pseudoephedrine products supplied to convenience stores. His analysis was debunked by Novelty and found unsupported by the ALJ, and not defended by the DA in her Order. *See D.C. Circuit Decision* at 1192 (Brown, J., dissenting) (citing Order at 52693-94); App. 40-41; *see also id.* at n.3 (Brown, J., dissenting) (commenting on the DEA's reliance on Robbin in more than twenty previous cases Judge Brown questioned, "How many jobs have been lost and reputations ruined because of this dubious analysis? One wonders if the DEA feels remorse for preying on companies that lack the wherewithal or sophistication to fight back against sloppy statistics."); App. 41.

nation in demand despite differences in demographics, weather, proximity to airborne pollutants, respiratory disease frequencies, store operating hours, and store proximity to other retail outlets and pharmacies. That reliance is not based on substantial evidence and should have been checked by effective federal judicial review.

3. The DA Shifted the Burden of Proof to Novelty to Explain Why Some Stores Sold More Than Others in Violation of 21 C.F.R. 1309.54(b)

In DEA registration revocation hearings, DEA has the burden of proving the requirements for revocation. 21 C.F.R. 1309.54(b). After using Novelty's average sales data to condemn it, the DA stated, "[Novelty] offered no explanation that was specific to any store for why it was selling in such quantities." Order at 52700; App. 114-115. Here, the DA holds Novelty to DEA's burden. Judge Brown condemned the burden shifting:

> But the burden of proof is on the government before it can take away someone's livelihood . . . and even if it were otherwise, this is an unfair obligation to spring on Novelty as the company was responding to the statistics of DEA's so-called expert – statistics that even the DA does not defend.

D.C. Circuit Decision at 1196-1197 (Brown, J., dissenting); App. 51. "This statistical inevitability is not something that a company should have to

explain, nor should the DEA be able to escape its burden . . . effortlessly." *Id.* The DA's unlawful burden shifting is now the rule of law because the D.C. Circuit condoned the practice. In her dissenting opinion, Judge Brown concluded, "If arbitrary and capricious is to mean anything . . . this decision cannot be allowed to stand." *Id.* at 1193; App. 42.

B. THE MAJORITY OPINIONS ARE CONTRADICTORY AND SHOULD NOT HAVE RESULTED IN AN ORDER UPHOLDING THE DA'S DECISION

The decisions of Judges Tatel and Henderson conflict. Judge Henderson finds that Novelty had to register every in-transit cross-dock as a "principal place of business" under 21 U.S.C. § 822(e). *See D.C. Circuit Decision* at 1184 (Henderson, K., concurring); App. 21. Judges Tatel and Brown reject that conclusion as contrary to the statute's plain meaning. *See id.* at 1187-1188 (Tatel, D., concurring) (holding the DA's interpretation of 822(e) invalid under *Chevron*); App. 27-31; *id.* at 1193-1195 (Brown, J., dissenting) (holding the DA's interpretation of 822(e) invalid under *Chevron*); App. 42-47. Judge Tatel illogically finds that although the cross-docks need not be registered, they must nonetheless meet security requirements applicable to registered locations (and, without facts of record to support, concludes they did not). *See id.* at 1188-1189; App. 28-33. The majority opinions of Judges Henderson and Tatel thus conflict. Violation of the CSA and revocation of

Novelty's registration should not be permitted to stand in such a circumstance.

Judges Brown and Tatel held the DA's interpretation patently unreasonable and, thus, unlawful, under step two of *Chevron U.S.A., Inc. v. Natural Resources Defense Council,* 467 U.S. 837 (1984). *See D.C. Circuit Decision* at 1187, 1193-1194; App. 27, 42-47. Following the canons of statutory interpretation, courts require agencies to give effect to every word in an enabling statute. *See Sierra Club v. EPA,* 536 F.3d 673, 680 (D.C. Cir. 2008) (citing *U.S. v. Menasche,* 348 U.S. 528, 538-539, 75 S.Ct. 513 (1955)) ("It is [a court's] duty to give effect, if possible, to every clause and word of a statute"). In the DA's Order she errs by making "surplusage of the word 'principal.'" *D.C. Circuit Decision* at 1187 (Tatel, D., concurring); App. 29; *see also id.* at 1193 (Brown, J., dissenting) (calling DA's interpretation "[H]ogwash" stating, "[e]ven with the winds of deference at its back, this interpretation of § 822(e) is a nonstarter. It reads the word "principal" out of a statute whose plain language requires . . . : (1) "distribut[ion]" from (2) a "principal place of business"); App. 43-44. The DA chose to expand the statute beyond its plain limits. As the "heart of the DA's analysis" this unreasonable reading creates agency precedent contrary to law and must be overturned. *Id.* at 1193; App. 42-43.

According to Judges Tatel and Henderson, however, if DEA's erroneous ruling on 21 U.S.C. § 822(e) were corrected, that would not affect the

ultimate outcome. *See PDK*, 362 F.3d 786 (administrative error deemed insufficient to justify remand unless rectification of it altered outcome).[30] Judge Brown disagreed, finding the DA's reliance on her erroneous statutory interpretation the "heart of" the DA's Order. *D.C. Circuit Decision* at 1193 (Brown, J. dissenting); App. 42-43. Judges Tatel and Henderson erred by invoking the harmless error rule on an issue of dispositive significance.

Under the multi-factor totality of the circumstances test prescribed by 21 U.S.C. § 823(h), the DA relied on Novelty's supposed violation of Section 822(e) to implicate three of four statutory public interest factors.[31] The DA predicated almost her entire decision on her erroneous construction of that section, *see* Order at 52698; App. 106-107, but the majority of the D.C. Circuit's panel held the DA's statutory construction in violation of 21 U.S.C. § 822(e). The DA's interpretation of that section was the only basis in her decision sufficient to support revocation. Thus, the DA's decision hinges on the weakest of reeds. Despite the DA's heavy reliance on

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[30] This Court has repeatedly recognized *PDK* as correct in *Shinseki v. Sanders*, 129 S.Ct. 1696, 1704, (2009); *Nat'l Assn. of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 659, 127 S.Ct. 2518, 2530 (2007); *Morse v. Frederick*, 127 S.Ct. 2618, 2642, 551 U.S. 393, 431 (2007) (Breyer, J., dissenting).

[31] *See* Order at 52698-52702 (citing use of the unregistered cross-dock storage sheds in her analysis under 21 U.S.C. § 823(h)(1), (2), and (4)); App. 104-127.

a violation of law a majority of the Court found not violated, the panel failed to remand the case to DEA.

The Order minus the alleged 21 U.S.C. § 822(e) violation, should equal the ALJ's recommended ruling (wherein the ALJ refused to address that alleged violation and held that Novelty should retain its registration).[32] The decision in *PDK* obligated the panel to remand with instructions not to consider Novelty's unregistered locations as law violations and, on that basis, to reconsider the prudence of the ALJ's recommended continued registration. *See PDK*, 362 F.3d at 794; *see also Fed. Express Corp. v. Mineta*, 373 F.3d 112, 118 (D.C. Cir. 2004) (remand is appropriate where "there is reason to think that the remand might lead to a different result"); *Mass. Trs. v. U.S.*, 377 U.S. 235, 248, 84 S.Ct. 1236 (1964) (upholding agency decision "when a mistake of the administrative body is one that *clearly had no bearing on* . . . the substance of decision reached") (emphasis added). Here, the DA deemed Novelty a blatant law breaker. That conclusion permeates her analysis. By contrast, the ALJ found Novelty to have demonstrated a history of compliance with the law. The statutory violation clearly impacted the totality of the circumstances test applied by the DA. A majority of the panel having found the interpretation incorrect should have reversed and remanded the decision to DEA.

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[32] *See* ALJ Decision at 91 n.38; App. 269.

The conflicted panel provides no guidance for the regulated industry, or constraints to prevent the DEA's continued unlawful enforcement. The legal issues on appeal remain unsettled. Although flawed, the majority opinion somehow binds the parties despite the absence of a consensus. Allowing the conflicted decision to stand is contrary to this Court's precedent and that of the D.C. Circuit. *See, e.g.,* Note, *Plurality Decisions and Judicial Decisionmaking*, 94 HARV. L. REV. 1127, 1130-1132 (1981) (explaining that fractured opinion relying on two distinct rationales results in a "false plurality decision" which "is completely useless as guides to lower courts . . . in resolving future cases, and to legislatures trying to cope with incomprehensible pronouncements" of law); *Neil v. Biggers*, 409 U.S. 188, 192, 93 S.Ct. 375 (1972) (explaining that an equally divided affirmance was not an actual adjudication barring subsequent consideration of the same issues and stating that, "[i]f the judges are divided, the reversal cannot be had, for no order can be made"); *Macklin v. Spector Freight Systems, Inc.*, 478 F.2d 979, 990 (D.C. Cir. 1973), *overruled on other grounds*, 421 U.S. 454; *U.S. v. Pink*, 315 U.S. 203, 216, 62 S.Ct. 552 (1942) ("the lack of an agreement by a majority of the Court on the principles of law prevents it from being an authoritative determination for other cases").

C. THE COURT CANNOT SUBSTITUTE ITS OWN REASONING *POST HOC* WHEN NO MAJORITY SUPPORTS THE DA'S REASONING

Judge Tatel's basis for revocation is not the DA's. Judge Tatel's is a *post hoc* rationalization, upholding the DA's revocation on two grounds: the security at Novelty's in-transit cross-docking stations and the precious few instances when Novelty customers sold in excess of Novelty's self-imposed (and not legally required) two 24 count package per transaction limit. The DA did not base her decision on those two factors. *See D.C. Circuit Decision* at 1188 (Tatel, D., concurring); App. 31-32.[33]

In her brief discussion of security at certain of Novelty's cross-dock storage units, the DA stated, "putting aside momentarily the issue of whether these storage units must be registered, it is *unlikely* that they could meet the security requirements of this Agency." Order at 52698 (emphasis added); App. 106-107. Thus the DA did not make a specific finding that the cross-docks did not, in fact, meet the security requirements of registered locations (there was no such issue in the OSC or adduction of requisite evidence at hearing). The DA speculated that lack of

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[33] *See* Order at 52703 (DA acknowledges the totality of circumstances test and states that "the Agency considers all of the facts and circumstances in determining the appropriate sanction"); App. 131; *see also* Order at 52691 (summarizing reasons for revocation); App. 68-69.

security at the storage units, if supported by DEA's burden of proof (which it was not), would "provide reason alone to support the finding that its continued registration is 'inconsistent with the public interest.'" *Id.* Judge Tatel reinterpreted that speculation as evidence supporting his *post hoc* rationalization. He did so inconsistently. He held the cross-docks were not legally required to be registered but upheld the DA's decision on the basis that the cross-docks had to meet the security requirements for registered locations (and he did so without requisite evidence to conclude that the cross-docks were inadequately secured).

The record shows that the cross-docks were secured with Novelty's own padlocks accessible only by keys issued to Novelty's truckers and their Novelty supervisors. *See* ALJ Decision at 16-17, 84; App. 161-162, 259. The cross-docks were ordinarily used to hold product for a matter of hours to permit transfer of goods from Novelty's long-distance trucks to Novelty's direct delivery trucks. *See id.* The security of the cross-docks was never a material issue in this case. DEA failed to raise the issue in the OSC; its investigators never investigated a single cross-dock to evaluate security. The DEA failed to present evidence that Novelty's cross-docks had ever been compromised or their goods stolen. The DA was thus unable to conclude them insecure, but Judge Tatel did so conclude.

Judge Tatel's reliance on this factor as a violation of the CSA is not supported by precedent. In two

previous applications submitted to the DEA (cited by the DA in her opinion) use of unsecured storage units was a factor among many in finding against registration of those applicants, but in neither case was it dispositive. *See* Order at 52698 (citing *Stephen J. Heldman*, 72 FR 4032, 4034 (2007) and *Sujak Distributors*, 71 FR 50102, 50104 (2006)); App. 106-107.[34] When stating her grounds, the DA included none that were later recited by Judge Tatel.[35]

The DA's Order must stand on its own; the D.C. Circuit is not empowered to uphold the decision on a rationale not appearing in the DA's Order. *See Clark County, Nev. v. FAA*, 522 F.3d 437, 441 (D.C. Cir. 2008) ("a court is not to substitute its judgment for that of the agency"); *see also Federal Power Commission v. Texaco, Inc.*, 417 U.S. 380, 397, 94 S.Ct. 2315 (1974) (court cannot accept *post hoc* rationalizations of appellate counsel). This Court, the D.C. Circuit, and the sister circuits have consistently

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[34] In *Sujak*, the DA's findings were part of a totality of the circumstances balancing wherein the respondent's lack of security was among other factors militating against registration. *See Sujak Distributors*, 71 FR at 50104 (2006).

[35] *See* Order at 52691 (DA summarizing her reasons for revoking Novelty's registration citing; first, Novelty did not maintain effective controls against diversion as a result of inadequate recordkeeping and distribution to some stores in excess of Novelty's average customer purchases; and second, Novelty violated 21 U.S.C. § 822(e) by not registering each cross-dock storage unit used in its distribution method) (all constituting grounds soundly refuted by Novelty); App. 68-69.

rejected *post hoc* rationalizations.[36] When the court creates justifications for agency action as a substitute for the agency's own, it transgresses the line between judicial review and executive action, involving the court in the business of agency policy and rule creation. That separation of powers is violated by the D.C. Circuit's reliance on the *post hoc* rationale in this case. *See Burlington Truck Lines v. U.S.*, 371 U.S. 156, 168, 83 S.Ct. 239 (1962); *Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 157 (1991); *see also AT&T Corp. v. FCC*, 220 F.3d 607, 631 (D.C. Cir. 2000) (decision on how to promote competition in local and long distance telephone markets was a policy judgment, therefore "it is for the agency – not this court – to make"); *Nat'l Treasury Emples. Union v. Chertoff*, 452 F.3d 839, 867 (D.C. Cir. 2006) (quoting *Harmon v. Thornburgh*, 878 F.2d 484, 494 (D.C. Cir. 1989). The Court was "obliged to respect 'the fundamental principle that agency

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[36] *See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 2866 (1983); *SEC v. Chenery Corp.*, 318 U.S. 80, 87, 63 S.Ct. 454 (1943); *Wedgewood Village Pharmacy v. DEA*, 50 F.3d 541, 550 n.13 (D.C. Cir. 2007); *U.S. v. Garner*, 767 F.2d 104, 116-117 (5th Cir. 1985); *UHFC Co. v. U.S.*, 916 F.2d 689, 699 (Fed. Cir. 1990); *Gifford Pinchot Task Force v. U.S. Fish and Wildlife Service*, 378 F.3d 1059, 1071 n.7 (9th Cir. 2004); *Marshall v. Lansing*, 839 F.2d 933, 943-944 (3d Cir. 1988); *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 79-80 (2d Cir. 2006); *W. Va. v. Thompson*, 475 F.3d 204, 212 (4th Cir. 2007); *Sierra Club v. Flowers*, 526 F.3d 1353, 1360 (11th Cir. 2008); *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1580 (10th Cir. 1994).

policy is to be made, in the first instance, by the agency itself – not by courts, and not by agency counsel' ").

By adopting a *post hoc* rationalization, the D.C. Circuit stepped outside its judicial role and assumed a legislative role. *NLRB v. Metro. Life Ins.* Co., 380 U.S. 438, 444, 85 S.Ct. 1061 (1965) ("[*post hoc* rationales] are incompatible with the orderly function of the process of judicial review").

CONCLUSION

For the forgoing reasons, this Court should grant this Petition.

Respectfully submitted,

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United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 14, 2009 Decided June 22, 2009

No. 08-1296

NOVELTY, INC.,
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION *ET AL.*,
RESPONDENTS

On Petition for Review of an Order
of the Drug Enforcement Administration

Jonathan W. Emord argued the cause for the petitioner.

Teresa A. Wallbaum, Acting Deputy Chief for Policy and Appeals, United States Department of Justice, argued the cause for the respondent. *Anita Gay*, Attorney, entered an appearance.

Before: HENDERSON, TATEL and BROWN, *Circuit Judges*.

Separate statements filed by Circuit Judge KAREN LECRAFT HENDERSON, Circuit Judge DAVID S. TATEL and Circuit Judge JANICE ROGERS BROWN.

ORDER

Novelty, Inc. petitions for review of the order of the United States Drug Enforcement Administration in *Novelty Distributors, Inc.*, 73 Fed. Reg. 52,689 (Sept. 10, 2008).

IT IS ORDERED that the petition for review be denied. Judge Henderson sets forth her reasons for denying the petition in her separate concurring statement, as does Judge Tatel in his separate concurring statement. Judge Brown dissents from the denial for the reasons stated in her dissent.

Per Curiam

KAREN LECRAFT HENDERSON, *Circuit Judge*, concurring:

Novelty, Inc. (Novelty) petitions for review of the order of the United States Drug Enforcement Administration (DEA), *Novelty Distributors, Inc.*, 73 Fed. Reg. 52,689 (Sept. 10, 2008) (Final Order), which revoked its registration to distribute list I chemical products pursuant to the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* (CSA or Act). For the reasons set out below, I conclude that Novelty's petition for review should be denied.

I.

The CSA requires "[e]very person who . . . distributes any . . . list I chemical [to] obtain annually a

registration issued by the Attorney General." 21 U.S.C. § 822(a)(1). Section 823(h) requires the Attorney General to "register an applicant to distribute a list I chemical unless [he] determines that registration of the applicant is inconsistent with the public interest." *Id.* § 823(h). The Attorney General considers five factors in determining whether registration is inconsistent with the public interest:

> (1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
>
> (2) compliance by the applicant with applicable Federal, State, and local law;
>
> (3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
>
> (4) any past experience of the applicant in the manufacture and distribution of chemicals; and
>
> (5) such other factors as are relevant to and consistent with the public health and safety.

Id. § 823(h). The Attorney General may suspend or revoke a registration if the registrant "has committed such acts as would render his registration . . . inconsistent with the public interest as determined under [21 U.S.C. § 823]." *Id.* § 824(a)(4). A list I chemical distributor must obtain a "[s]eparate registration . . . at each principal place of business or professional

practice where [it] . . . distributes . . . list I chemicals." *Id.* § 822(e). The Attorney General has delegated the authority to deny, revoke or suspend registration to the DEA Administrator, 28 C.F.R. § 0.100(b), who has redelegated to the Deputy Administrator (DA). *Id.* § 0.104.

Novelty is an Indiana-based wholesale distributor of retail products to approximately 10,000 convenience stores in the United States, including over-the-counter pharmaceutical products containing ephedrine and pseudoephedrine. The CSA defines ephedrine and pseudoephedrine as "list I chemicals." 21 U.S.C. § 802(34)(C) & (K). Ephedrine and pseudoephedrine have legitimate uses[1] but they can also be diverted for use in the manufacture of methamphetamine, a schedule II controlled substance. *Id.* § 812(c); 21 C.F.R. § 1308.12(d). In 1998, the DEA granted Novelty a certificate of registration authorizing it to distribute list I chemical products from its Greenfield, Indiana facility. The DEA renewed Novelty's registration annually until 2008.

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[1] "Pseudoephedrine is a decongestant used for the temporary relief of nasal congestion due to the common cold, hay fever, or other upper respiratory allergies. Ephedrine is used for the temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma." DEA, Security Requirements for Handlers of Pseudoephedrine, Ephedrine, and Phenylpropanolamine, 69 Fed. Reg. 45,616, 45,616 [sic] (July 30, 2004).

According to Novelty's president,[2] Novelty stores its list I chemical products in a secure area in its registered Greenfield, Indiana warehouse. Administrative Hearing Transcript at 131-32, *Novelty Distributors,* Docket No. 08-33 (DEA Mar. 24 – Apr. 1, 2008) (Hearing Tr.). Only employees who pass a background check and receive training are authorized to enter the secure area. Each Novelty sales representative services approximately 80 convenience store customers and makes deliveries to each customer approximately every two weeks. According to Novelty's vice president of product, the customer tells the sales representative how many list I chemical products it needs and the sales representative orders them from Novelty's Greenfield facility. Novelty drivers transport the list I chemical products weekly in company trucks to approximately 150 self-storage units that Novelty rents from independent self-storage facilities throughout the country. Novelty informs its sales representative of the time of delivery to the self-storage unit. The list I chemical products typically remain in the self-storage unit anywhere from a few hours to two days until the sales representative transfers them to his vehicle for delivery to the customer. Each self-storage unit is locked and has varying degrees of additional security as provided by the individual

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[2] Novelty's president as well as other Novelty officials and various DEA personnel testified at the administrative hearing held to decide whether Novelty's registration should be revoked. *See infra* at 9.

storage facilities. According to Novelty's president, "there are cameras around . . . a lot of [the storage facilities]," "[t]hey have access points" and "[t]hey have codes to get into places." *Id.* at 131. One Novelty sales representative testified that the self-storage unit he used had only a padlocked door for security. *Id.* at 538. None of Novelty's approximately 150 self-storage units is registered with the DEA

Novelty sells combination ephedrine and pseudoephedrine products of different strengths and in varying quantities per package and it carries more than ten product lines containing list I chemicals. Novelty's vice president of product testified that Novelty limits each convenience store customer to one case of each product type per the sales representative's bi-weekly delivery to reduce the risk of diversion. According to Novelty's director of category management, Novelty enforces its one case per product type limit by issuing a warning to a noncompliant sales representative for a first infraction and terminating him for a second infraction. In addition, Novelty ceases selling list I chemical products to any customer purchasing in excess of one case per product type. Novelty's director of category management testified that between January 2007 and January 2008, there were approximately 35 to 45 violations of the one case limit of an estimated 100,000 to 120,000 total transactions. According to one of the DEA investigators who testified, however, Novelty violated its one case limit 85 times between January and July 2007. According to another DEA investigator, during

a November 2002 raid on an illegal methamphetamine lab in Connecticut, the DEA discovered ephedrine product manufactured by DMD Pharmaceuticals (DMD). DMD informed the DEA that in September 2002 it had shipped the product to Novelty for distribution. When the DEA contacted Novelty, Novelty was unable to identify the convenience stores that had purchased the ephedrine product later diverted.

On May 5, 2004, Dan Raber, Diversion Group Supervisor in the DEA's Indianapolis District Office, sent Novelty and other Indiana registrants a letter regarding the transportation and delivery of list I chemical products to retailers. Letter from Dan E. Raber, Diversion Group Supervisor, to Novelty Distributors, *Novelty Distributors*, Docket No. 08-33 (May 5, 2004) (Raber Letter). The Raber Letter specifically addressed the practice of "storing List I chemical products (including over-the-counter ephedrine and pseudoephedrine items) and distributing them from satellite locations, such as commercial storage units, personal residences and or delivery vehicles." *Id.* at 1. It "remind[ed] all registrants that 'any . . . distribution from[ ] a location other than the registered location (including the use of delivery vehicles for overnight storage) is a violation of federal law.'" *Id.* According to Novelty's vice president of product, Novelty concluded that it had to register all 150 self-storage units or stop using the units for list I chemical products, which it declined to do. In September 2004, it filed suit in the Southern District of

Indiana seeking a declaratory judgment that the Raber Letter constituted a rule making conducted without the requisite notice and comment. *Novelty, Inc. v. Tandy,* No. 04-cv-1502, 2006 WL 2375485, at *1 (S.D. Ind. Aug. 15, 2006). Almost four years later, on August 7, 2008, the district court granted the DEA's motion for summary judgment, concluding that the Raber Letter was an interpretive rule that did not require notice and comment.[3] *Novelty, Inc. v. Tandy,* No. 05-cv-1502, 2008 WL 3835655, at *16 (S.D. Ind. Aug. 7, 2008).

On January 17, 2008, the DA suspended Novelty's registration and issued an order to show cause why the DEA should not revoke Novelty's registration, setting forth several grounds therefor. Order to Show Cause and Immediate Suspension of Registration, *Novelty Distributors,* Docket No. 08-33 (DEA Jan. 17, 2008) (Suspension Order). First, Novelty used unregistered self-storage units to distribute list I chemical products, a factor weighing against Novelty's continued registration under 21 U.S.C. §§ 823(h)(2) (noncompliance with applicable laws) and 824(a)(4) (acts inconsistent with public interest). *Id.* at 1. Second, Novelty distributed list I chemical products to its customers in quantities greater than could be used for legitimate purposes, a factor weighing

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[3] From the Raber Letter's issuance in May 2004 until the Suspension Order issued in January 2008, Novelty continued using the self-storage units for distribution of list I chemical products. *See infra* at 19-20.

against Novelty's continued registration under 21 U.S.C. § 823(h)(1) (ineffective controls against diversion). *Id.* at 2. Third, Novelty maintained inaccurate records in violation of 21 U.S.C. § 830(a) (record keeping requirements for list I chemical transactions) and 21 C.F.R. § 1310.04.[4] *Id.* Fourth, Novelty distributed ephedrine and pseudoephedrine products to retailers that were not self-certified as required by 21 U.S.C. § 830(e)(1)(B)(i).[5] *Id.* Fifth, Novelty distributed list I chemical products packaged in a form that did not comply with 21 U.S.C. § 830(d)(2).[6] *Id.* at 2-3.

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[4] A distributor must keep records of "regulated transaction[s] involving a listed chemical . . . for two years after the date of the transaction." 21 U.S.C. § 830(a). The records must be "retrievable and shall include the date of the regulated transaction, the identity of each party to the regulated transaction, a statement of the quantity and form of the listed chemical, a description of the tableting machine or encapsulating machine, and a description of the method of transfer." 21 U.S.C. § 830(a)(2); *see also* 21 C.F.R. § 1310.04 (tracking 21 U.S.C. § 830(a)).

[5] "A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted to the Attorney General the self-certification referred to in subparagraph (A)(vii)." 21 U.S.C. § 830(e)(1)(B)(i). Subparagraph (A)(vii) requires a seller to "submit [ ] to the Attorney General a self-certification that all [employees of the seller who deliver list I chemical products to the consumer's custody] have . . . undergone training provided by the seller." *Id.* § 830(e)(1)(A)(vii).

[6] "With respect to ephedrine base [or] pseudoephedrine base . . . in a scheduled listed chemical product . . . a seller or distributor may not sell such a product in nonliquid form (including gel caps) at retail unless the product is packaged in blister packs, each blister containing not more than 2 dosage units, or where the use of blister packs is technically infeasible, the

(Continued on following page)

Sixth, Novelty distributed list I chemical products in Kentucky and North Carolina in a form (tablets instead of gel-caps) prohibited by their respective state laws. *Id.* at 3. Based on the above-cited grounds, the DA found that "the scheduled listed chemical products distributed by Novelty have been, and are likely to continue to be, diverted into the illicit manufacture of methamphetamine" and that "Novelty has failed to maintain effective controls against such diversion as required by 21 U.S.C. § 823(h)(1)." *Id.* Accordingly, the DA concluded that "Novelty's continued registration . . . would constitute an imminent danger to the public health and safety." *Id.*

Shortly after the Suspension Order issued, Novelty approached an ephedrine product manufacturer proposing that Novelty act as its sales agent. Novelty offered to receive retailers' orders for ephedrine products and then transmit the orders to the manufacturer. The manufacturer would then use a third-party shipper to "distribute" the ephedrine products directly to the retailers. Under Novelty's proposal, the retailer itself could either prepare[7] the ephedrine product for sale or the Novelty sales representative could do so when he next called on the retailer. The manufacturer rejected the proposal.

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product is packaged in unit dose packets or pouches." 21 U.S.C. § 830(d)(2).

[7] Preparation for sale involves removing the ephedrine product from the box in which it is shipped and placing the product in the retailer's secure display cabinet.

Novelty requested a hearing before an administrative law judge (ALJ) as allowed by the Suspension Order. The hearing was held from March 24 to April 2, 2008. The ALJ then issued her decision, rejecting the charges that Novelty had (1) distributed list I chemical products to retailers that were not self-certified, (2) distributed ephedrine products packaged in a nonconforming way and (3) distributed ephedrine products in Kentucky and North Carolina in violation of state law. Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the ALJ, *Novelty Distributors,* Docket No. 08-33, at 37-40, 71-72, 78-79 (DEA May 21, 2008) (ALJ Decision). The ALJ found, however, that Novelty did not maintain effective controls against diversion under 21 U.S.C. § 823(h)(1) based both on its record-keeping errors and on multiple violations of its one case per product type limit.[8] The ALJ declined to decide whether 21 U.S.C. § 822(e) (requiring "separate registration at each principal place of business" where list I chemicals are distributed) required Novelty to register its self-storage units because of the then-pending litigation regarding the Raber Letter in the Southern District of Indiana. *Id.* at 91 n.38. Nevertheless, the ALJ did find that Novelty had a duty to comply with the Raber Letter until the litigation challenging Raber's interpretation of the statute was resolved, which duty Novelty failed to meet and, as a consequence thereof,

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[8] The DA cited the DMD Pharmaceuticals diversion, *supra at* 5, as evidence thereof. Final Order at 52,694.

Novelty's failure weighed in favor of revocation under 21 U.S.C. § 823(h)(2). *Id.* at 91. While the ALJ found that the first two factors listed in section 823(h) supported the conclusion that Novelty's continued registration was inconsistent with the public interest, she found that the third factor (prior convictions), fourth factor (past distribution experience) and fifth factor (other considerations) weighed in Novelty's favor and thus were consistent with the public interest under 21 U.S.C. § 823(h)(3), (4) and (5), respectively. The ALJ recommended that the DA "levy compliance requirements upon [Novelty]."[9] *Id.* at 101. On review, the DA instead revoked Novelty's registration. Final Order at 52,704. Novelty timely petitioned for review under the Administrative Procedure Act, 5 U.S.C. § 702, and the CSA, 21 U.S.C. § 877.

II.

Under the APA, we must "set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "Findings of fact by the Attorney General [are conclusive] if supported by substantial evidence." 21 U.S.C. § 877. We "'may not find substantial evidence merely on the basis of evidence which in and of itself justified [the

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[9] The ALJ recommended that the DA "use her discretion to levy compliance requirements upon [Novelty] to a degree that would satisfy the DEA that [Novelty] is operating [sic] with the DEA to protect the public interest." ALJ Decision at 101.

agency's decision], without taking into account contradictory evidence or evidence from which conflicting inferences could be drawn.'" *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) (quoting *Lakeland Bus Lines, Inc. v. NLRB*, 347 F.3d 955, 962 (D.C. Cir. 2003) (internal quotations omitted)) (alteration in *Morall*). The DEA is the ultimate fact finder but "[t]he agency's departures from the [ALJ's] findings are vulnerable if they fail to reflect attentive consideration to the [ALJ's] decision." *Id.* (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 853 (D.C. Cir. 1970)) (first alteration added). To uphold agency action, we must determine "that the agency examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* (quoting *El Rio Santa Cruz Neighborhood Health Ctr. v. U.S. Dep't of Health & Human Servs.*, 396 F.3d 1265, 1276 (D.C. Cir. 2005) (internal quotations omitted)) (alteration in original). In determining the public interest under the factors set forth in 21 U.S.C. § 823(h), the DA need not "make findings as to all of the factors enumerated. . . . Rather, he may give each factor the weight he deems appropriate." *Id.* at 173-74 (internal quotations omitted) (ellipsis in original). We "review the DA's decision[ ], insofar as [it] interpret[s] statutes, under the standard articulated by the Supreme Court in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)." *Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 549 (D.C. Cir. 2007). Under *Chevron* step 1, if a statute is unambiguous,

then we "must give effect to the unambiguously expressed intent of Congress." *Chevron,* 467 U.S. at 843. If the statute is ambiguous, we move to *Chevron* step 2 and "must defer to the agency's interpretation as long as it is 'based on a permissible construction of the statute.'" *Creekstone Farms Premium Beef, L.L.C. v. Dep't of Agric.,* 539 F.3d 492, 498 (D.C. Cir. 2008) (quoting *Chevron,* 467 U.S. at 843). Although Novelty raised a host of objections both to the DA's investigation and to the Final Order, I conclude that only the following merit discussion.[10]

A.

Novelty argues that the DA failed to consider contradictory evidence and failed to explain her departure from the ALJ's recommended sanction. Novelty lists numerous facts favorable to it that the

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[10] Novelty made the following additional objections: (1) the DA imposed a no-risk standard on distributors of list I chemical products to convenience stores and small retailers contrary to "congressional intent," Pet'r Br. at 31; (2) the DA did not articulate a discernible standard of acceptable risk of diversion, *id.* at 32; (3) the DA's revocation of Novelty's registration was part of a biased enforcement campaign against distributors of list I chemical products to convenience stores and small retailers, *id.* at 33-35; (4) the DA exhibited prejudgment bias, *id.* at 38-43; *see generally Withrow v. Larkin,* 421 U.S. 35, 47 (1975); and (5) DEA agents imposed a prior restraint – in violation of the First Amendment to the United States Constitution – on Novelty's video and audio recording of DEA investigators while they conducted their investigation of Novelty, Pet'r Br. at 43-47. I reject these objections as meritless.

ALJ relied upon but that the DA allegedly disregarded. Pet'r Br. at 23-30. Contrary to Novelty's assertion, the DA referenced most of the listed facts in her Final Order. Those facts not explicitly mentioned – such as areas of Novelty's distribution system free of the risks she identified in other areas – are either irrelevant to the DA's reasoning or of little weight, such as the fact that many of Novelty's packages were secured with plastic zip-ties. I can "reasonably discern," *ACS of Anchorage, Inc. v. FCC*, 290 F.3d 403, 408 (D.C. Cir. 2002), that the DA considered the holes she identified in Novelty's distribution system to be serious notwithstanding an otherwise compliant background; that is, to find Novelty's distribution system flawed, she was hardly required to identify every non-flawed aspect of it.

The DA also adequately explained why she revoked Novelty's registration despite the ALJ's recommendation to impose compliance conditions. The DA acknowledged that "the evidence points to some measures which [Novelty] voluntarily undertook" to prevent diversion. Final Order at 52,703. But the DA found that "these measures do not address the serious problems with its distribution practices that are established by the record, and which were either ignored, or discounted by the ALJ." *Id.* The ALJ found that Novelty's "10 year history of compliance, as evidenced by the DEA's continued registration," weighed against revocation. ALJ Decision at 100-01. The DA did not regard Novelty's registration renewals as "probative of a registrant's record of compliance,"

stating that "[t]here are a variety of reasons why the Agency may not be prepared to go forward with a Show Cause Proceeding at a particular time including, *inter alia,* a lack of resources, the complexity of the matters under investigation, and the need to pursue other enforcement priorities." Final Order at 52,702 n.53. The ALJ viewed favorably Novelty's "willingness to comply with the laws and regulations," ALJ Decision at 98, but the DA was not persuaded by Novelty's willingness to change because of the "sustained nature of the violations and [its] failure to voluntarily cease its misconduct."[11] Final Order at 52,703. I conclude that the Final Order "reflect[s] attentive consideration to the [ALJ's] decision," *Morall,* 412 F.3d at 177 (internal quotations omitted) (alteration in original), and took into account contradictory evidence.

B.

Novelty argues that the CSA does not require it to register its rented self-storage units. The CSA requires "[a] separate registration . . . at each principal place of business or professional practice where

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[11] As noted earlier, after the Suspension Order issued, Novelty approached an ephedrine manufacturer about acting as the latter's sales agent, *see supra* at 8, rather than either registering each of the self-storage units or discontinuing their use. At the time of the hearing, moreover, a Novelty executive testified that the sales agent proposal was "[s]omething that we're still continuing to explore." Hearing Tr. at 2403.

the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals." 21 U.S.C. § 822(e); *see also* 21 C.F.R. § 1309.23(a) ("A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed. . . ."). "[D]istribute" means "to deliver (other than by administering or dispensing) a controlled substance or a listed chemical." 21 U.S.C. § 802(11). "Deliver" means "the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship." *Id.* § 802(8).

Novelty makes two arguments to support its reading of section 822(e) not to require the registration of each of the self-storage units. First, it asserts that each self-storage unit is not a "place of business . . . where [it] . . . *distributes* . . . list I chemicals." *Id.* § 822(e) (emphasis added). I disagree. A Novelty truck driver transports the ephedrine products from the Greenfield, Indiana facility to the self-storage unit, where the ephedrine products remain for several hours or days. The sales representative then transfers the products to his vehicle for delivery to Novelty's convenience store customers. The unit is therefore a "place of business" because it is a "general physical location" whence Novelty distributes ephedrine products. 21 C.F.R. § 1309.23(a). In other words, the Novelty sales representative distributes

the ephedrine products from the self-storage units to retailers.[12]

Second, Novelty argues that each self-storage unit is not a "*principal* place of business." 21 U.S.C. § 822(e) (emphasis added). The CSA does not define "principal place of business." The word "principal" means "most important, consequential, or influential." Merriam-Webster's Third New Int'l Dictionary Unabridged 1802 (1993); *see also United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 123 (5th Cir. 1991) (defining "principal" in 21 U.S.C. § 822(e) as "important [or] consequential" (quoting Webster's New Collegiate Dictionary 908 (1979)) (alteration in original)). While the statute does not require registration of every place of business whether or not it is a "principal" one, as the DA correctly noted, the statute plainly contemplates the existence of more than one "principal place of business" as manifested by the use of "each" in requiring "each principal place of business" to be registered. *See* Final Order at 52,701. Nevertheless, in my view, "principal" – as used in section 822(e) – is ambiguous because the

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[12] Both parties note that the DEA excepts from registration "[a] warehouse where List I chemicals are stored by or on behalf of a registered person, *unless such chemicals are distributed directly* from such warehouse *to locations other than the registered location* from which the chemicals were originally delivered." 21 C.F.R. § 1309.23(b)(1) (emphases added). Because Novelty's list I chemical products *are* distributed directly from the self-storage units to customers, the units do not come within the warehouse exception.

Congress has not supplied criteria, e.g., a minimum percentage of total products distributed from a location, to guide the DEA. I am therefore required to reach *Chevron* step 2. *See Pub. Serv. Co. of Colo. v. FERC*, 91 F.3d 1478, 1482 (D.C. Cir. 1996). The DEA must decide which "place[s] of business" are "principal" in each registrant's distribution system. I must examine whether its reading – requiring Novelty to register the self-storage units – is "based on a permissible construction" of 21 U.S.C. § 822(e). *Chevron*, 467 U.S. at 843.

Notwithstanding Novelty's assertion that each self-storage unit "processes a small fraction of Novelty's total [list I chemical] product[s] shipped nationwide," Pet'r Br. at 49, *all* of the list I chemical products it distributes passes through a self-storage unit. Moreover, as noted earlier, the DA permissibly found that the products remain at the units for up to several days at a time. Each storage unit is therefore "important" and "consequential" to Novelty's distribution system. The DA's interpretation of "principal" also correctly relied on the statutory context.[13] *See*

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[13] The DA noted:

> Congress imposed on a registrant the obligation to obtain a separate registration at "*each* principal place of business * * * where the applicant * * * distributes * * * List I chemicals." 21 U.S.C. 822(e) (emphasis added). . . . In determining whether a facility is a principal place of business within the meaning of the CSA, the Act looks to the nature of the activity that occurs at the particular location and not at the dollar

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Pharm. Research & Mfrs. of Am. v. Thompson, 251 F.3d 219, 224-25 (D.C. Cir. 2001) (examining context, including statutory purpose, in interpreting statute's wording). The DA also rejected Novelty's interpretation because it "would clearly frustrate the Congressional purpose." Final Order at 52,701.

> In enacting the CSA's registration provisions, Congress' purpose was to protect against diversion by requiring that those persons who propose to engage in the legitimate distribution of controlled substances and listed chemicals apply for a registration, notify this Agency of the proposed location of their activity, and submit the facility for inspection by the Agency to ensure that it has adequate security controls and procedures. *See, e.g.*, 21 U.S.C. 822(f) (authorizing the Attorney General "to inspect the establishment of a registrant or applicant for registration"). Indeed, inspection by the Agency of a proposed facility is fundamental to the CSA's mandate to protect the public interest. *Id.* 823(h); *see also* 21 CFR 1309.41.

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volume of business that is transacted out of the facility. *See* 21 CFR 1309.23(b)(2) (exempting from registration "[a]n office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals . . . nor serves as a distribution point for filling sales orders").

Final Order at 52,701 (alteration of statute and regulation in original).

Id.; *see also* 21 C.F.R. § 1309.71 (listing factors DA must consider in evaluating effectiveness of security controls and procedures). The DEA cannot inspect a facility it either does not know exists or the location of which it does not know.

The DA also noted the "perverse incentive" created by interpreting "principal" based on the volume of business at a particular location instead of the nature of that business. Final Order at 52,701. An interpretation "which determines whether a facility must be registered by looking to the amount of business activity that occurs out of a facility rather than the nature of the activity that occurs therein, would encourage an entity to keep adding warehouses or storage facilities so that it could eventually claim that its warehouses were no longer principal places of business and were thus not subject to the registration requirement." *Id.*

I conclude that the DA reasonably construed 21 U.S.C. § 822(e) to require that each of Novelty's self-storage units is a "principal place[s] of business" subject to the registration requirement.[14]

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[14] As my dissenting colleague points out, *Dissenting Opinion* at 7, the DA concluded that section 822(b) "requires that *a separate registration be obtained at each location at which List I chemicals are distributed.*" Final Order at 52,700 (emphasis in original). Because, as the DA found, Novelty's self-storage units fit within the statutory language of a "principal place of business . . . where [Novelty] . . . distributes . . . list I chemicals," *id.* § 822(e), I do not reach her more general pronouncement that

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C.

Finally, Novelty challenges the DA's reliance on several facts in support of revocation.[15] First, Novelty argues that its failure to enforce its one case of each ephedrine product per sales visit limit did not violate any statute or regulation but instead its self-imposed

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every place of business where list I chemicals are distributed must be registered.

[15] Novelty also challenges the sufficiency of the evidence to support the DA's finding that Novelty distributed list I chemical products in excess of legitimate demand to some convenience stores. Final Order at 52,699-700. At the hearing, the DEA's expert witness testified that the average monthly expected retail value of list I chemical products to satisfy legitimate demand is $14.39 per convenience store. Both the ALJ and the DA rejected the DEA expert's legitimate demand analysis and his conclusion that any ephedrine product sale above $14.39 per month was presumably diverted to methamphetamine manufacturing. Final Order at 52,694. The DA used a different method to determine excessive distribution. She compared the average monthly retail value of list I chemical products distributed to each Novelty customer during the three months before the Suspension Order issued with the average monthly retail value of list I chemical products distributed by Novelty to all of its customers. A Novelty executive testified that, on average, Novelty distributed list I chemical products with a retail value of approximately $640 to each customer per month. But the DA found that within three months of the Suspension Order's issuance, Novelty distributed list I chemical products with an average monthly retail value in excess of $2,000 to approximately 120 customers, in excess of $4,000 to 9 customers and in excess of $7,000 to one customer. *Id.* at 52,699. While I question the probative value of looking at sales that "greatly exceed[ ]" the average without statistical analysis, *id.* at 52,700, I need not reach the issue because I conclude that the Final Order is supported on other grounds, *see infra* note 17.

limit. But the DA did not conclude that Novelty violated any law by not enforcing its limit. Novelty asserted that its one case limit constituted an effective control against diversion and the DA rejected the one case limit as an effective control because Novelty did not enforce it, a finding the evidence supports. *See* Final Order at 52,693 (Novelty sales representatives violated one case limit 85 times between January and July 2007).

Second, Novelty argues that it should not be penalized for continuing to use self-storage units while its challenge to the Raber Letter was pending in the Southern District of Indiana. *See id.* at 52,703 ("[Novelty]'s disregard of the letter and continuation of its practices for some forty-four months makes its conduct especially egregious."). Novelty stopped distributing list I chemical products – and thus stopped using the self-storage units for the products – once the Suspension Order issued on January 17, 2008. The Indiana district court rejected Novelty's challenge to the Raber Letter on August 7, 2008. In revoking Novelty's registration, the DA relied on Novelty's failure to register the self-storage units following the Raber Letter and its failure to enforce its one case limit as evidence that compliance conditions alone would not protect the public interest. *Id.* Novelty argues that its failure to register the self-storage units does not demonstrate its unwillingness to comply because its non-compliance was based on its good faith belief that the Raber Letter was invalid, as evidenced by its legal action challenging the

letter.[16] Who was responsible for Novelty's continued use of self-storage units *pendente lite* – whether Novelty because it did not seek to stay the Raber Letter or the DEA because it did not attempt to enforce the Raber Letter until some forty months after issuance – we do not decide inasmuch as the DA found that Novelty's "failure to enforce its own policies [i.e., the one-case limit] provides reason alone to conclude it cannot be trusted to adhere to compliance conditions." Final Order at 52,704. As the DA's sanction would have been the same even absent this factor, I need not review her analysis of it. *See PDK Labs. Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration."). For similar reasons, I need not reach the question whether the DA erred in finding that Novelty "attempt[ed] to circumvent the suspension order," Final Order at 52,703, by proposing acting as a sales agent.[17]

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[16] Novelty also asserted that its legal challenge to the Raber Letter was motivated by its belief that using the common carrier alternative to deliver list I chemical products to its customers created a higher risk of diversion than its distribution system. Pet'r Br. at 55; Final Order at 52,701. The DA rejected Novelty's assertion, concluding that Novelty produced no evidence of diversion when products were shipped by common carrier. Final Order at 52,701-02.

[17] As noted earlier, between the Suspension Order and the ALJ's decision, Novelty proposed to an ephedrine products manufacturer that Novelty act as its sales agent. The CSA exempts from registration "[a]n agent or employee of any registered

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manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment," 21 U.S.C. § 822(c)(1), and thus, according to Novelty, had the manufacturer agreed, Novelty would have been exempt from registration.

My dissenting colleague believes that I must decide the circumvention issue and remand if I disagree with the DA, relying on *PDK Laboratories Inc. Dissenting Opinion* at 16. Assuming without concluding that I did in fact disagree with the DA on this point, *PDK Laboratories Inc.* would not support remand here. In *PDK Laboratories Inc.*, we vacated the DA's decision and remanded for the DA to reconsider his interpretation of a statute. 362 F.3d at 797-99. We then noted that even if we had upheld the DA's statutory interpretation, we "would still have to vacate the [DA's] decision and remand the case" because the DA had failed to distinguish DEA precedent in finding certain regulatory violations. *Id.* at 798-99. The DA made his decision based on "the totality of the circumstances" and "four of the 'circumstances' prominently mentioned were [the regulatory] . . . violations." *Id.* at 799. We found it "impossible to discern" the "weight he gave to those circumstances" and noted that, if the DA concluded on remand that the petitioner's actions were not regulatory violations, the outcome could change. *Id.* In contrast, the DA's conclusion that Novelty attempted to circumvent the Suspension Order is not a "prominent" reason for the Final Order revoking Novelty's registration. The DA concluded that the first (maintenance of effective controls against diversion) and second (statutory compliance) factors under 21 U.S.C. § 823(h) "*strongly* support[]" revocation. Final Order at 52,700, 52,702 (emphasis added). She found that the fourth factor (past distribution experience) and fifth factor (other considerations) "*also* support[]" revocation. *Id.* at 52,702-03 (emphasis added). The sole consideration under the fifth factor was Novelty's "attempt to circumvent the suspension order." *Id.* at 52,703. In selecting a sanction, the DA cited, first, Novelty's failure to register the self-storage units and, second, Novelty's failure to enforce its one case limit, *id.*, concluding, as noted above,

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Third, Novelty argues that substantial evidence does not support the finding that Novelty had "serious recordkeeping deficiencies." Final Order at 52,698. A registrant must "provide effective controls and procedures to guard against theft and diversion of List I chemicals," 21 C.F.R. § 1309.71(a), which includes maintaining "systems for monitoring the receipt, distribution, and disposition of List I chemicals." *Id.* § 1309.71(b)(8); *see also id.* § 1310.03 (list I chemical products distributors must keep record of all regulated transactions and file reports with DEA). The records must be "readily retrievable and available for inspection." *Id.* § 1310.04(d). Novelty does not dispute the fact of the record keeping deficiencies the DA cited in support of her finding, *see* Final Order at 52,698-99, but instead asserts they do not add up to inadequate records. Pet'r Br. at 57-58. The DA cited the fact that Novelty was missing invoices for sales of list I chemical products and that its records contained inadequate and inaccurate information regarding shipment dates and delivery locations. Final Order at 52,698-99. I conclude that these deficiencies support

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"[Novelty's] failure to enforce its own policies provides reason alone to conclude that it cannot be trusted to adhere to compliance conditions." *Id.* at 52,704. She found "further support[ ]" for revocation – as opposed to imposing compliance conditions – in Novelty's "sustained and flagrant violations of Federal law, as well as its attempt to circumvent the suspension order." *Id.* Accordingly, Novelty's alleged attempt to circumvent the Suspension Order was merely an additional factor supporting revocation and, if incorrect, would not have altered the outcome. Remand is therefore unnecessary.

the finding that Novelty's "failure to maintain adequate records . . . constitutes . . . a violation of Federal law." *Id.* at 52,699; *see* 21 U.S.C. § 830(a) (record keeping requirements for list I chemical transactions). I also reject Novelty's assertion that the DA did not adequately explain her disagreement with the ALJ's description of Novelty's records as "thorough." ALJ Decision at 84. But the ALJ also found several errors in Novelty's records, concluding that they were "not adequate to conduct an effective audit of [Novelty's list I chemical] products." *Id.* at 86, 88. The DA as the ultimate fact-finder is entitled to ascribe different significance to the deficiencies of Novelty's records. *Cf. Reckitt & Colman, Ltd. v. Adm'r,* 788 F.2d 22, 26-27 (D.C. Cir. 1986). Accordingly, I reject Novelty's sufficiency challenge to the evidence supporting the DA's deficient record keeping finding.

For the foregoing reasons, I conclude that Novelty's petition for review should be denied.

TATEL, *Circuit Judge*, concurring in the judgment:

Although troubled by several aspects of the Deputy Administrator's decision, I concur in the denial of the petition for review because substantial evidence supports two of her findings, which together constitute sufficient and independent grounds for the sanction of revocation.

Unlike Judge Henderson, I believe that the Deputy Administrator unreasonably construed section 822(e). That section requires a separate registration for "each principal place of business . . . where the applicant . . . distributes . . . list I chemicals." 21 U.S.C. § 822(e). This provision is hardly unambiguous as to the "precise question at issue," *Chevron U.S.A., Inc. v. Natural Res. Def. Council,* 467 U.S. 837, 842 (1984), i.e., whether the word "principal" can apply to places such as Novelty's self-storage units. The word "each" prevents "principal" from taking its ordinary meaning of "*most* important, consequential, or influential: relegating comparable matters, items, or individuals to secondary rank," WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1802 (1993) (emphasis added). Given this ambiguity, we must accept the Deputy Administrator's construction if reasonable. *See Chevron,* 467 U.S. at 843.

Judge Henderson reads the Deputy Administrator as finding that certain characteristics of Novelty's self-storage units made them sufficiently "consequential" to the company's operations for the units to constitute principal places of business under section 822(e). Op. at 15-17. Although I think it quite counterintuitive that anyone would ever describe a self-storage unit as a "principal place of business" for a corporation with hundreds of employees and a nationwide client base, that interpretation might well be defensible as a reasonable exercise of the Deputy Administrator's authority to interpret an ambiguous provision of the Act. *See id.* But because it isn't the

interpretation on which the Deputy Administrator actually relied, we may not use it to sustain her action. *See, e.g., PDK Labs. Inc. v. DEA*, 362 F.3d 786, 798 (D.C. Cir. 2004) ("[I]f we find that an agency's stated rationale for its decision is erroneous, we cannot sustain its action on some other basis the agency did not mention." (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 200 (1947))).

Instead of determining that the self-storage units were "consequential" due to their particular status in Novelty's business structure, *see* Op. at 15-16, the Deputy Administrator determined they were "consequential" (and thus "principal") simply because they were locations from which Novelty distributed list I chemicals, *Novelty Distributors, Inc.* ("*Final Order*"), 73 Fed. Reg. 52,689, 52,700 (Sept. 10, 2008). Making this interpretation quite clear, she stated that section 822(e) "requires that a separate registration be obtained at *each* location at which List I chemicals are *distributed*." *Id.* at 52,700 (internal quotation marks and some emphasis omitted); *see also id.* (explaining DEA's position that "[t]he person who distributes List I chemicals from independently owned warehouses *must register at each location*" (internal quotation marks omitted, alteration in original)).

The Deputy Administrator's interpretation suffers from a fatal flaw – it makes surplusage of the word "principal." If all locations where an applicant distributes list I chemicals must be registered, then the phrase "each principal place of business . . . where the applicant . . . distributes . . . list I chemicals"

would mean exactly the same thing if the word "principal" disappeared. Although "principal" as used in section 822(e) could have several permissible readings, any reasonable interpretation must impose some limitation not already captured by the term "distributes." *See* Dissenting Op. at 7-8; *see also, e.g., Sierra Club v. EPA*, 536 F.3d 673, 680 (D.C. Cir. 2008) ("It is a court's duty to give effect, if possible, to every clause and word of a statute." (internal quotation marks, brackets and ellipsis omitted)).

To be sure, in the course of explaining her interpretation the Deputy Administrator did say at one point that "[a] location where List I chemicals are stored and distributed from, is a principal place of business because it plays a 'consequential' part in the registrant's activity of distributing." *Final Order*, 73 Fed. Reg. at 52,701. Although a requirement that list I chemicals be "stored" at a location could supplement the requirement that they be distributed, the word "stored" instead seems little more than a verbal flourish. After all, it's mentioned only in passing during the Deputy Administrator's argument for her expansive interpretation and never makes its way into any narrowing formulation. Clearly, then, as the Deputy Administrator sees it, "*each* location at which List I chemicals are distributed," *id.* at 52,700 (some emphasis omitted), must be registered, not just those locations at which the chemicals are also stored. Given that the word "stored" fails to avoid surplusage, the Deputy Administrator's interpretation is thus unreasonable under *Chevron* and cannot support

her conclusion that Novelty failed to comply with applicable law.

But this does not end the matter, for the Deputy Administrator placed independent reliance on two findings unrelated to her flawed statutory interpretation. Each finds support in the record, and together they form a sufficient basis for the sanction imposed.

First, the Deputy Administrator found that whether or not section 822(e) required their registration, the self-storage units posed a serious risk of diversion. *See* 21 U.S.C. § 823(h)(1) (requiring consideration of the registrant's maintenance of effective controls against diversion). She stated that it was "unlikely" that the units would meet DEA's security requirements, citing agency precedent finding that the use of similar units posed "an unacceptable risk of diversion." *Final Order,* 73 Fed. Reg. at 52,698. She also pointed to several flaws in Novelty's storage units, such as the fact that the door of one unit was accessible to the public. *Id.* Finally, she noted that even by the time of her decision Novelty had failed to provide DEA with accurate locations for thirty-four of its storage units. *Id.* For all of these reasons, the Deputy Administrator concluded that Novelty's "use of these storage facilities . . . does not provide adequate controls against diversion and provides *reason alone* to support the finding that its continued registration is inconsistent with the public interest." *Id.* (emphasis added, internal quotation marks omitted). Read in context as part of a discussion of the adequacy of Novelty's controls against diversion, this

statement amounts to a finding that the company's use of the self-storage facilities posed risks of diversion sufficient to show that Novelty failed to maintain effective diversion controls. *See id.* at 52,700 (finding that this factor supports revocation). And as Judge Henderson explains, the Deputy Administrator adequately addressed contrary evidence in making this finding. *See* Op. at 12.

Second, and just as important, when turning to the choice of sanction, the Deputy Administrator stated that Novelty's failure to enforce its own diversion control policies "provides *reason alone* to conclude that it cannot be trusted to adhere to compliance conditions," *Final Order,* 73 Fed. Reg. at 52,704 (emphasis added) – the only lesser sanction under consideration. Substantial evidence supports this conclusion. The Deputy Administrator found that on 85 occasions during a six-month period, Novelty violated its policy limiting customers to one case per sales cycle. *Id.* at 52,703. Novelty insists the policy applied only to certain packages and was thus violated just 35 to 45 times in a one-year period. Petr.'s Reply Br. 19. But the Deputy Administrator credited testimony establishing that the policy applied to a wider range of packages and thus that Novelty in fact committed 85 violations, Hr'g Tr. at 624. Contrary to the dissent, the Deputy Administrator had no obligation to consider how many completed transactions were made during that six-month period, *see* Dissenting Op. at 14, because many of the completed transactions may have been ones in which

the customer only demanded one case, and thus would hardly count as instances of successful enforcement of the one-case limit. The Deputy Administrator was also skeptical of Novelty's failure to issue warnings to its sales force until after DEA's administrative inspection warrant, permissibly discrediting testimony that this delay stemmed from a computer glitch. *Final Order,* 73 Fed. Reg. at 52,703; *see also* Hr'g Tr. at 1435.

The Deputy Administrator made several additional points that support her finding that Novelty failed to enforce its own policies. She observed that the record contained no evidence that Novelty ever completely cut off any of the stores that violated the one-case policy (as the company's CEO promised he would). *Final Order,* 73 Fed. Reg. at 52,703; *see also* Hr'g Tr. at 159. She also pointed out that Novelty sold extremely high quantities of list I products to one store even after the company itself became concerned that the store was making excessive purchases, inferring from this that Novelty's "policy of monitoring unusual sales activity and cutting off sales if such purchases continue is a sham and not a legitimate effort to control diversion." *Final Order,* 73 Fed. Reg. at 52,703-04 (internal quotation marks and citation omitted). This inference is perfectly rational, though I hasten to add that I wouldn't necessarily agree with the Deputy Administrator's more general treatment of high sales volumes as prima facie evidence of diversion. It's one thing to infer, as the Deputy Administrator did here, *id.,* that Novelty's high

volume of sales to a store that it had previously found made excessive purchases indicates that Novelty isn't serious about its policy of monitoring suspicious transactions. It's quite another to infer, as the Deputy Administrator did elsewhere, *id.* at 52,700, that similarly high volumes of sales made to stores never suspected of suspicious activity signal a high risk of diversion. But only the former, more sensible inference is necessary to the sanction imposed.

According to the Deputy Administrator, her finding that Novelty failed to enforce its own policies provided "reason alone" to reject sanctions short of revocation. *Id.* at 52,704. The dissent believes that the Deputy Administrator couldn't have meant what she said given that she spent much of her opinion enumerating additional factors favoring revocation. Dissenting Op. at 16 n.10. But agencies often enumerate multiple grounds for their actions, even when one or more of the grounds would be adequate standing alone. By referring to this finding as "reason alone" to reject lesser sanctions, the Deputy Administrator clearly did so here.

Together, these two findings – that Novelty's use of self-storage units rendered its delivery system unsecure and that its disregard of its own policies required revocation – provided an independent basis for the Deputy Administrator's action. I thus have no need to address Novelty's objections to (1) the Deputy Administrator's treatment of high sales volumes as prima facie evidence of diversion, (2) its finding that Novelty attempted to circumvent the order

suspending it from distributing list I chemicals, or (3) its condemnation of Novelty's use of the self-storage units while challenging the Raber letter. Although I am somewhat troubled by the first two, none of these challenges could possibly affect the outcome of this petition for review given the Deputy Administrator's reliance on independent and sufficient grounds for revocation. *See PDK Labs.*, 362 F.3d at 799 ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration.").

I agree with Judge Henderson that Novelty's other objections to the Deputy Administrator's decision are without merit. The Deputy Administrator correctly concluded that even if DEA agents violated the First Amendment during their inspection of Novelty's warehouse, the exclusionary rule is inapplicable to administrative proceedings of the kind at issue here. *See Pa. Bd. of Prob. & Parole v. Scott*, 524 U.S. 357, 363 (1998) ("[W]e have repeatedly declined to extend the exclusionary rule to proceedings other than criminal trials."). Novelty complains that the Deputy Administrator failed to articulate the level of tolerable risk, but the Raber letter gave perfectly adequate guidance. Finally, neither Novelty's complaint that the Deputy Administrator conducted a biased campaign of enforcement against independent distributors of list I chemicals nor its complaint of unconstitutional prejudgment bias finds support in the record. Especially given the Deputy Administrator's rejection of much of the government's

evidence, my concerns with her reasoning fall short of the level at which "a disinterested observer may conclude that [the Deputy Administrator] has in some measure adjudged the facts as well as the law of a particular case in advance of hearing it," *Cinderella Career & Finishing Sch., Inc. v. FTC,* 425 F.2d 583, 591 (D.C. Cir. 1970) (internal quotation marks omitted).

BROWN, *Circuit Judge*, dissenting: Tellingly called poor man's crack (especially telling, as crack is already poor man's cocaine), methamphetamine – meth – is a national scourge. Behind only "alcohol and marijuana as the drug used most frequently in many Western and Midwestern states," Methamphetamine, http://www.usdoj.gov/dea/concern/meth.html (last visited May 19, 2009), meth addiction can cause "paranoia, auditory hallucinations, mood disturbances," and even "homicidal or suicidal thoughts," Meth Awareness, http://www.usdoj.gov/methawareness/ (last visited May 19, 2009). "A fairly common hallucination experienced by meth users is the so-called crank bug" where a "user gets the sensation that there are insects creeping on top of, or underneath, her skin," causing her to "pick at or scratch her skin trying to get rid of the imaginary bugs," "open[ing] sores that may become infected." *Id.* Meth also "reduces the amount of protective saliva around the teeth," which, along with the fact that "users also consume excess sugared, carbonated soft drinks, tend to neglect personal hygiene, grind their teeth and clench their

jaws," causes "what is commonly called 'meth mouth,'" as addicts' teeth "fall out" "even as they do simple things like eating a sandwich." *Id.* Meth is a very bad thing. A monster.

But we don't toss the law aside in our zeal to eradicate even an obvious menace. The Deputy Administrator (DA) here has done just that,[1] in the process crippling a successful enterprise and costing many employees their jobs. In rejecting the ALJ's recommendation that Novelty be allowed to retain its registration, the DA transforms a trivial violation of Novelty's own rules into an imminent danger to the public health and shifts the burden to Novelty to explain why some of the thousands of convenience stores it services are busier than others. Subject to this perverse alchemy, ordinary business practices somehow provide proof of rampant lawlessness. Thus, the DA (1) misreads a statute so any place used for distribution is a "principal place of business," even a padlocked storage shed; (2) uses the average sales of every convenience store serviced by Novelty as a

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[1] As the Administrative Law Judge (ALJ) perceptively observed, no party "dispute[s] that illegal methamphetamine is a major drug problem in the United States," but the agency "seems to be trying to remedy this problem by restricting or eliminating the availability of such over-the-counter products by removing the distributors of [these] products to convenience stores from the market place" altogether, despite lacking sufficient record evidence. *In re Novelty Distrib.*, No. 08-33, slip op. at 93 (May 21, 2008) (Recommended Ruling of the Administrative Law Judge) ("*ALJ Ruling*").

proxy for legitimate demand at each location without regard to any individual characteristics; and (3) finds Novelty's efforts to stay in business after its registration was suspended to be proof of villainy.[2] Because "[t]he war on drugs is not an excuse to violate the norms of fair play and evenhandedness," *United States v. Cuellar*, 478 F.3d 282, 307 (5th Cir. 2007) (en banc) (Smith, J., dissenting), *rev'd* 128 S. Ct. 1994 (2008), I respectfully dissent.

I.

To appreciate how poorly supported the DA's decision really is, a little history is helpful. This case first came before us when Novelty challenged the DA's suspension order, but the DA mooted that initial challenge by revoking Novelty's registration before oral argument. To justify that initial suspension, the DA gave five reasons why Novelty's continued operations endangered the public. First, Novelty violated 21 U.S.C. § 822(e) by distributing from unregistered locations. *In re Novelty Distrib.*, Order to Show Cause

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[2] Alas, these are not the only things the Drug Enforcement Administration (DEA) did wrong. Agents interfered with Novelty's understandable efforts to document in real time the search of the company's own facility by forbidding the use of and disabling video and audio recorders. These agents also "requested 12,000 additional pages of documents," giving only "three hours to produce them," and an executive believed he would be arrested because he could not do the impossible. *ALJ Ruling*, slip op. at 62-65. Such tactics do not reflect well on the United States.

& Immediate Suspension of Registration, slip op. at 1 (Jan. 17, 2008). Second, Novelty sold products to stores in amounts that "far exceeded what those retail outlets could be expected to sell for legitimate, therapeutic purposes," and some drugs were diverted to a Connecticut meth lab in 2002. *Id.* at 2. Third, Novelty "could not account for more than 60,000 dosage units of two ephedrine products," and there were other gaps in the company's records. *Id.* Fourth, "[f]rom January 1, 2007, through July 9, 2007, Novelty distributed scheduled listed chemical products on at least 284 occasions to 35 retail outlets that were not self-certified under" federal law. *Id.* Finally, Novelty distributed products in unlawful containers and in forms that violated state laws. *Id.* at 2-3.

The case went before an ALJ, who rejected most of these allegations as factually unsupportable. For instance, it's just not true that Novelty distributed drugs to stores that were not self-certified. *ALJ Ruling,* slip op. at 91. Nor did Novelty sell drugs in forms or packages that violated any law. *See id.* at 37-39. And the DEA's audit failed to consider all the data it received from Novelty: "Specifically, the DEA had failed to take into account dosage units returned to vendors, data that had been removed from the inventory because of expired or obsolete inventory, and other unspecified documents reflecting miscellaneous transfers or adjustments." *Id.* at 87-88. Based on the evidence, the most that could be said about those "60,000 dosage units" was that Novelty's record-keeping was inadequate. *Id.* at 88. In her revocation

decision, the DA conceded the ALJ was correct on these points. *See Novelty Distrib., Inc.*, 73 Fed. Reg. 52689, 52695 (Sept. 10, 2008) (Revocation of Registration) ("At most, the evidence suggests that [Novelty] made a single distribution to a single store before it obtained its certification."); *id.* at 52695-96 (form and packaging); *id.* at 52696-97 (audit).

The ALJ also debunked the DEA's argument that Novelty was selling over-the-counter drugs in amounts that exceeded legitimate demand. Jonathan Robbin, the DEA's expert, concluded "a convenience store is expected to sell no more than $14.39 worth of . . . products per month," even though one 24-count package could cost up to $14.99. *ALJ Ruling,* slip op. at 96 & n.40. In other words, selling even one package per month would be suspicious. The ALJ set forth the flaws in this analysis. Robbin, for example, used the wrong denominator, thereby "forcing a lower expected sales value." *Id.* at 55. He did "not provide a detailed breakdown" of how he determined important inputs in his formula, "other than providing a narrative of his approach," and he offered data about the entire retail industry and just not convenience stores. *Id.* He ignored that much of his data relied on self-reporting, and instead of reporting sales as "cold and cough products," some stores used the "general merchandise" category. *Id.* at 56-57 n.28. He also did not do a multivariate analysis to consider "[f]actors such as store hours, store location, store size, advertising expenditures, and management practices," or other "seasonal and environmental variables." *Id.* at 58.

Unsurprisingly, the DA did not defend Robbin's analysis. 73 Fed. Reg. at 52693-94.[3]

Thus, all that lingered of the DA's aggressive allegations was that Novelty broke the law by using unregistered storage units; that Novelty's records were deficient in certain respects; and that a small amount of product had been diverted. In revoking Novelty's registration, the DA also emphasized Novelty's letter to one of its suppliers that supposedly manifested an intent to circumvent the suspension

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[3] Though the DA did not uphold Robbin in this case, he has been relied upon in more than twenty other cases, even though his approach – aside from being internally defective – does not appear even to yield consistent results. *Compare Sunny Wholesale, Inc.*, 73 Fed. Reg. 57655, 57658 (Oct. 3, 2008) ("Mr. Robbin explained . . . that during 2005, '[t]he expected average monthly convenience store sales of nonprescription drug products containing pseudoephedrine (hcl) in Georgia were * * * $82.'") *with Holloway Distrib.*, 72 Fed. Reg. 42118, 42119 (Aug. 1, 2007) ("Mr. Robbin explained that a monthly retail sale of $60 of pseudoephedrine (Hcl) * * * would be expected to occur less than one in 1,000 times in random sampling, and a monthly retail sale of . . . $100 in pseudoephedrine (Hcl) . . . would occur about once in a million times in random sampling.") *with H & R Corp.*, 71 Fed. Reg. 30168, 30169 (May 25, 2006) ("Mr. Robbin . . . determined that the normal expected retail sales of pseudoephedrine tablets in a convenience store would . . . average . . . about $20.00 and the sales of more than $100.00 in a month would be expected to occur in a random sampling about once in one million to the tenth power, a number he characterized as nearly equivalent to the number of atoms in the universe."). How many jobs have been lost and reputations ruined because of this dubious analysis? One wonders if the DEA feels remorse for preying on companies that lack the wherewithal or sophistication to fight back against sloppy statistics.

order, and that Novelty did not comply consistently with its own anti-diversion rules. Finally, because Robbin's statistics were useless, the DA invented, seemingly *sua sponte,* a new statistical analysis, placing the burden on Novelty to rebut it. These grounds, though much less compelling than the grand claims made in the suspension order, were enough for the DA to shut down Novelty's list I chemicals operations for good.

To say the case for revocation is razor thin greatly exaggerates its sufficiency. As the statute is written, the storage units are not illegal. The DA's newly-concocted statistics are just as bad as Robbin's, and the "smoking gun" letter is anything but. Moreover, though Novelty did not always live up to its own policies, mistakes were rare, and the DA failed to even consider the relevant denominator. True, company records were somewhat deficient, but no DEA agent had ever before complained of Novelty's "thorough" records, despite multiple inspections, *ALJ Ruling,* slip op. at 84, 93, and, in any event, the DA said if the only problem were recordkeeping, "imposing compliance conditions might well protect the public interest." 73 Fed. Reg. at 52703. If "arbitrary and capricious" is to mean anything in the DEA context, this decision cannot be allowed to stand.

II.

The heart of the DA's analysis – that unregistered storage units *always* violate federal law –

contradicts the statute, *Chevron* notwithstanding. Under no reasonable reading does 21 U.S.C. § 822(e) require each link in the distribution chain to be registered. Nonetheless, in revoking its registration, the DA gave top billing to Novelty's supposed lawbreaking: "First, for more than three and a half years, Respondent disregarded a DEA letter specifically warning it that its use of 150-180 self-storage units . . . violated Federal law." 73 Fed. Reg. at 52703. In fact, not only did the DA lean on this finding for purposes of 21 U.S.C. § 823(h)(2) (compliance with law), she double-dipped and used again it for § 823(h)(4) (past experience). *See id.* at 52702. But she was wrong; it was not Novelty that bent the law.

Section 822(e) says a "separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals." 21 U.S.C. § 822(e). Novelty argued its scores of run-of-the-mill self-storage units were not "principal places of business," and thus did not need to be registered. The DA rejected this position, determining that federal law "requires that *a separate registration be obtained at each location at which List I chemicals are distributed.*" 73 Fed. Reg. at 52700.

Hogwash. Even with the winds of deference at its back, this interpretation of § 822(e) is a nonstarter. It reads the word "principal" out of a statute whose plain language requires two things: (1) "distribut[ion]" from (2) a "principal place of business." The question is simple: if *all* locations where distribution occurs

must be registered, why would Congress specifically refer to "each *principal* place of business"? To make the word "principal" disappear, the DA resorted to magic tricks. She determined each "location" where "List I chemicals are . . . distributed from" is a "principal" one because it "plays a 'consequential' part in the registrant's activity of distributing." *Id.* at 52701 (quoting WEBSTER'S THIRD NEW INT'L DICTIONARY 1802 (1976)).[4] Hence "principal place of business where a registrant distributes list I chemicals" = "consequential" place of business = "each location where list I chemicals are distributed." (abracadabra omitted). But after the smoke fades away, the DA's approach to the word "principal" causes § 822(e) to read like this: "A separate registration shall be required at each location where list I chemicals are distributed where the applicant distributes list I chemicals." That is a silly way to read a statute. *E.g., Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979) ("In construing a statute we are obliged to give effect, if possible, to every word Congress used.").

To be sure, § 822(e) contains ambiguity, as it invokes a common term of art in a way that is not consistent with its ordinary usage. "Principal place of

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[4] The relevant definition of "principal" is: "1: *most* important, consequential, or influential: relegating comparable matters, items, or individuals to secondary rank." WEBSTER'S THIRD NEW INT'L DICTIONARY 1802 (1976) (emphasis added). Though the DA elected to not even quote it, much less consider it, 73 Fed. Reg. at 52701, the word "most" is particularly meaningful.

business" is most prominently used in 28 U.S.C. § 1332(c), relating to corporate diversity, and it is settled that for diversity jurisdiction there can only be one "principal place of business." *E.g., Capitol Indem. Corp. v. Russellville Steel Co.*, 367 F.3d 831, 835 (8th Cir. 2004). Section 822(e), by use of the word "each", contemplates multiple such places. But just because a statute is ambiguous does not mean any interpretation of it is reasonable. *See, e.g., Int'l Alliance of Theatrical and Stage Employees v. NLRB*, 334 F.3d 27, 34-35 (D.C. Cir. 2003). Though the language here cannot mean the exact same thing as in § 1332(c), it is unreasonable to find that any place where distribution occurs is per se "principal." No matter how defined, "principal place of business" surely means more than *that*. If every place is "principal," no place is.

The DA mused, however, that any other reading than hers "would clearly frustrate the Congressional purpose," which was to prevent "diversion by requiring that those persons who propose to engage in the legitimate distribution of . . . listed chemicals apply for a registration, notify this Agency of the proposed location of their activity, and submit the facility for inspection . . . to ensure that it has adequate security controls and procedures." 73 Fed. Reg. at 52701. For this proposition, she cited 21 U.S.C. 822(f), which reads: "The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him." This is not at

all sufficient to support her construction of § 822(e) as "establishment" – used in § 822(f) – is not the same as "principal place of business." The surest Rosetta Stone into "Congressional purpose" is the language Congress actually uses, but the DA's construction of § 822(e) effectively deletes Congress's word "principal" from the U.S. Code.

The DA then explained that accepting Novelty's view "would also create a perverse incentive" for registrants to "keep adding warehouses or storage facilities so that it could eventually claim that its warehouses were no longer principal places of business and thus were not subject to the registration requirement." 73 Fed. Reg. at 52701. Perhaps, but if records are kept at these hypothetical warehouses, if employees work there full-time, if they are listed in the phone book, if drugs are kept there for an indefinite duration, and so on, then there may be an argument that these warehouses are "principal places of business." The DA did not even attempt to offer such a nuanced test. Instead, she found all storage units must, as a matter of law, be registered. How is a shed, locked with a padlock, a "principal place of business" for a company like Novelty with hundreds of employees and thousands of customers across the nation?[5]

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[5] As the ALJ found, nearly all Novelty's sales were to "major retail convenience store chain customers" – "'billion dollar companies'" with "full-time staff" and "legal counsel, to ensure

(Continued on following page)

What is most aggravating is that reading the statute correctly would not create the dire dichotomy painted by the DA, one in which any other view but hers would "render the Act a nullity." *Id.* The DEA still has recourse to the first factor under 21 U.S.C. § 823(h), relating to the risk of diversion. If a registrant's distribution practices are not safe, that problem can be addressed by the statutory scheme *as written*. There is no need to mangle the text to make unsafe distribution an independent violation of federal law. However, instead of simply relying on that first § 823(h) factor (perhaps because there is almost zero evidence of actual diversion), the DA adopted an atextual claim of lawbreaking to bolster the argument in favor of revocation.

III.

The DA also botched her diversion analysis. Let's be clear: there is remarkably little evidence of actual diversion in this record. The best the DA can muster is an event from 2002 when "twenty-two [sixty-count bottles of an ephedrine-based product] were found at an illicit methamphetamine laboratory in Thompson, Connecticut." 73 Fed. Reg. at 52694. Novelty, however, did not produce those bottles, and it is uncertain whether the company even distributed them. *See ALJ Ruling,* slip op. at 74. The DEA, it seems, also never

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compliance with state and federal regulations." *ALJ Ruling,* slip op. at 6.

formally warned Novelty about the diversion until it took action against the company in 2008. 73 Fed. Reg. at 52702. But even given the benefit of the doubt, the DA can only point to one instance of diversion, despite Novelty's *hundreds of millions* of doses sold.[6] *See, e.g.*, Pet'r's Br. at 15 (Novelty has sold between three and five hundred million doses).

Because proof of actual diversion was paltry, revocation rested on Novelty's theoretically ineffective controls against diversion. There is much in the DA's reasoning that I sympathize with; I too wonder whether it is prudent to keep drugs in storage sheds or on trucks for over a week.[7] Likewise, though her concern about Novelty's recordkeeping was overstated, I agree it is important to keep complete records, and if Novelty had concerns about a particular store, it should have been especially vigilant. At the

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[6] DEA investigators also "visited a number of [Novelty's] customers," and, after looking at the "logbooks" used to record drug sales, found five stores with questionable patterns (though not all sales were illegal, they nonetheless were "suspicio[us]"). 73 Fed. Reg. at 52694-95. Novelty, however, "cannot review the logbooks." *Id.* at 52699 n.43. The DEA, it seems, did not investigate further to see if these drugs were being illicitly used.

[7] I am confused, however, about the logic in the Raber Letter. Registrants are allowed to keep drugs in the truck "overnight" for "long delivery route[s]," provided the delivery is for "*pre-placed customer specific orders for List I chemical products.*" Raber Letter. But if the concern is "a thief can steal the vehicle's cargo," 73 Fed. Reg. at 52698, then why does it matter if the drugs are for "pre-placed customer specific orders" or for on-site orders?

same time, as the ALJ found, Novelty took "a proactive role in ensuring its customers are self-certified," made sure its customers used "lockable, plexiglass display cases for the display and sale of" drugs, and "when the DEA brought the recordkeeping errors" to Novelty's attention, Novelty "identified a reasonable reason for the errors, and acted to correct those errors by upgrading its computer system." *ALJ Ruling,* slip op. at 98-99. Novelty also credibly offered to modify its distribution network to address safety concerns. *Id.* at 100-01. (The DA wrongfully rejected the ALJ's credibility finding based on her erroneous belief that the storage units were illegal, 73 Fed. Reg. at 52703). Given the large number of transactions, moreover, some mistakes will happen; what human endeavor is done perfectly millions of times in a row? Nonetheless, there is some reason to conclude Novelty's protections against diversion – even if factually "effective," as the statute requires, 21 U.S.C. § 823(h)(1) – were imperfect, though such oversights should be addressed by compliance conditions far short of the corporate death penalty that is revocation.

But instead of just relying on this theoretical diversion, the DA went further and reasoned Novelty's own statistics "showing its sale of [drugs] in the three months prior to the issuance of the suspension order" demonstrated that Novelty did not maintain effective controls against diversion. 73 Fed. Reg. at 52699. The support for that claim is embarrassingly weak. Despite the almost self-evident fact that not all convenience stores are created equal (for instance, the

AM/PM next to a major freeway may be a lot busier than Ma's Gas-N-Go in Middle-of-Nowhere Alabama), the DA conjured a very blunt instrument to derive legitimate market demand: Novelty's average sales data. Instead of relying on a multivariate statistical study that could have accounted for factors affecting sales at individual stores, she operated on an unstated assumption that every store in the country should request an amount close to the average, meaning any request above the average suggests a likelihood of diversion. But what a store should request is based on legitimate, non-diversionary demand for the product *at its location*. Just as a store selling below the national average might still show a risk of diversion if it requests many more drugs than non-diversionary demand would warrant at its location, a store selling above the average does not show a diversion risk if it requests the amount which would be expected at its location. The DA's approach ignored this basic and obvious point.

Similarly, as Novelty's expert observed, "if an average legitimate sales figure was derived from data from both high-sales revenues stores and low-sales revenues stores, but then that average legitimate sales figure was used to predict sales in only the high-sales revenues stores, the prediction would suffer from aggregation bias." Instead of accepting this unassailable logic, the DA said "proof that a distributor is selling quantities in excess of the national monthly average of sales of [drugs] by convenience stores would be highly probative of the distributor's lack of

effective controls against diversion." 73 Fed. Reg. at 52700. This tells us very little about anything; after all, 50% of all convenience stores should be expected to have sales greater than the average.

The DA then said "[m]ore specifically, a registrant cannot ignore evidence that some of its customers are purchasing quantities that greatly exceed what its typical customer buys from it." *Id.* This statement, of course, seems a little more persuasive (but only a little); if one assumes all convenience stores are similar, and if a store is receiving many more drugs than others, that should raise a red flag – but, of course, not all stores are similar. The DA concluded by stating Novelty "offered no explanation that was specific to any store for why it was selling in such quantities." *Id.* But the burden of proof is on the government before it can take away someone's livelihood, *see* 21 C.F.R. § 1309.54(b), and even if it were otherwise, this is an unfair obligation to spring on Novelty as the company was responding to the statistics of DEA's so-called expert – statistics that even the DA does not defend, 73 Fed. Reg. at 52693-94. In any event, there is no basis to shift the burden to Novelty because we should expect statistical outliers. *See id.* at 52700 n.45. Of the thousands of stores serviced by Novelty across the country in countless different climes and circumstances, is it really unthinkable that a small subset of them will be much busier than the others? This statistical inevitability is not something that a company should have

to explain, nor should the DEA be able to escape its burden of proof so effortlessly.[8]

The DA's problems with large numbers do not end there. Ignoring that no complex system can be 100% foolproof, the DA applied an unreasonable zero-tolerance standard that Congress surely did not intend.[9] She found, for example, that Novelty "violated its case limit policy [i.e., its *own* policy that it would only sell one 24-count package to a store per visit] some 85 times" during a six-month period, 73 Fed. Reg. at 52699. That sounds pretty bad, but the DA omitted the denominator; according to the record, the number of transactions during that year was "approximately 100,000 to 120,000." The error rate thus may have been less than .2% (no one knows for sure the exact rate because the DA did not even attempt to discern it using any methodology whatsoever, Judge Tatel's or otherwise, *see* Tatel Op. at 4-5). Despite the

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[8] Novelty, moreover, showed no reluctance to police its own operations. When Store # BPM55, its largest customer, purchased noticeably large quantities – *although not more than federal law allowed* – Novelty prohibited the sale of 100-count ephedrine to that store. Perhaps Novelty could have done more, but if a single debatable judgment call about what extralegal steps must be taken to avoid diversion can cost a company its registration, then all the world's a cage, with every registrant just waiting to be culled.

[9] Just as "safe" does not mean "risk-free," *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 642 (1980) (Stevens, J., plurality), "maintenance by the applicant of *effective* controls against diversion" as used in 21 U.S.C. § 823(h) cannot mean *perfect* controls, an impossible standard.

burden resting with the government, the DA did not explain how much risk is too much, nor did she give any context to those "85" violations (a number, by the way, that Novelty says is at least forty too high). All we know is sales staff may have mistakenly sold extra packages of product to convenience stores – not to meth makers, mind you – less than two times per thousand transactions. Yet somehow Novelty's "failure to enforce its own policies provides reason alone to conclude that it cannot be trusted to adhere to compliance conditions"? 73 Fed. Reg. at 52704.

IV.

In revoking the registration, the DA also stressed Novelty's attempt to find a new way of doing business once its registration was suspended. Though conceding Novelty did nothing illegal, she nonetheless found Novelty did more than "merely think[ ] about a legal option or seek[ ] legal advice about the scheme," but also "affirmatively sought out one of its suppliers and attempted to induce it to enter the scheme only to be rebuffed by the supplier." 73 Fed. Reg. at 52703. The DA concluded "[i]t would fundamentally undermine the [Controlled Substance Act's] purpose of protecting against diversion to allow an entity whose registration has been revoked to subsequently engage in the same or related activities as an agent." *Id.*

Here are the real facts. In January 2008, the DEA suspended Novelty's registration. After receiving the suspension order, Novelty sent a letter, which I

quote, explaining its "plan to get back in the ephedrine business" to one of its suppliers. Letter from Novelty, Inc. (under seal). Under the "plan" – which was "still [being] finaliz[ed] . . . with the DEA to insure everything can work smoothly and we do not have any issues" and was awaiting "approval" before any sales would occur – Novelty's sales force would "tak[e] orders" which would be sent "to a third party logistics company for shipping and handling" to "fill the order . . . via UPS or similar carrier." *Id.* The "costs [to the owner of the store would] remain the same," and "[a]ll invoices [would be] from Novelty." *Id.* The owner of the store would "have the choice of stocking the [drug] cabinet or holding it for [Novelty's] sales person." *Id.* The effect would be to "basically keep[ ] the business the same," except with "a UPS box." *Id.* The supplier declined to participate, but a Novelty executive testified during the administrative process that Novelty was "still continuing to explore" this idea.

The DA's reading of the letter is unfair. Making tentative plans – plans contingent upon DEA authorization no less – suggests nothing nefarious. Novelty, moreover, planned on substantially changing its business, including no longer using its own distribution network (i.e., the very network at issue in this case). Under 21 U.S.C. § 822(c)(1), a sales agent need not be registered if he "is acting in the usual course of his business or employment," which, under this completely new business model, seemingly would include Novelty. Granted, Novelty said its plan would

"basically keep[ ] the business the same," but, in context, the only plausible reading of the sentence is the business would remain the same for Novelty's customers, not for Novelty itself. How could the business be unchanged for Novelty which would not longer do the shipping and handling of these drugs?

Neither of my colleagues reaches this issue (though both hint they might agree with my analysis). This is a mistake. The DA employed a totality of the circumstances test, but the only evidence she relied upon in assessing 21 U.S.C. § 823(h)(5) – the statute's catch-all category – was Novelty's letter. *See* 73 Fed. Reg. at 52702-03. Because the DA erred as to this factor, and because we do not know how much weight she gave it in her analysis,[10] at a minimum this court should remand for her to reweigh the evidence. *See, e.g., PDK Labs., Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand

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[10] In context, I charitably assume the DA's otherwise staggering suggestion that Novelty's "failure to enforce its own policies provides reason alone to conclude that it cannot be trusted to adhere to compliance conditions" was not intended to be taken literally, particularly as it was not the first reason given for revocation, 73 Fed. Reg. at 52703-04, and if Novelty's failure to self-police were intended to be sufficient on its own, then there was no reason for the rest of the DA's lengthy opinion. But if the statement was not hyperbole, then we obviously should vacate this decision because, as explained, the DA entirely failed to consider the relevant denominator. What can be more arbitrary and capricious than that?

for reconsideration. But in this case we cannot say that the Deputy Administrator's error was of that sort. . . . [as he] stated that it was 'the totality of circumstances' that led him to sustain the suspension orders.").

* * *

I close with a few words on how easily the administrative state can slip its leash. A familiar argument for enhanced administrative authority (and hence diminished judicial review) is the need for "flexibility," as old-fashioned courts are ill-suited to deal with the complexities of the modern world. *E.g.*, Cass R. Sunstein, *Law and Administration After Chevron,* 90 COLUM. L. REV. 2071, 2079 (1990) (citing, *inter alia,* J. LANDIS, THE ADMINISTRATIVE PROCESS 6-12 (1938)). That may be true. But the flipside of flexibility is certainty, consistency, evenhandedness, and predictability – those Rule of Law values that mark a free society. *E.g.*, THOMAS PAINE, COMMON SENSE 31-32 (Dover Thrift ed., 1997) (1776) ("[L]et a crown be placed thereon, by which the world may know, that so far as we approve of monarchy, that in America THE LAW IS KING. For as in absolute governments the king is law, so in free countries the law *ought* to be king; and there ought to be no other."). If my splintered-on-seemingly-all-points-but-outcome colleagues are right that despite her many errors, the DA's decision to revoke Novelty's registration still must be upheld, then I fear we have traded away far too much law in our bargain for elasticity.

But in the end, because of this "flexibility," it is probably for the best that the DA's decision is upheld today. If the registration was not revoked this time, it surely would have happened next time. On this record, I have no confidence that Novelty would ever receive a fair shake from the DEA. Indeed, if we were reviewing a district court that acted like this, I would not remand to that court. But the DEA is the only game in town for drug registrants, and in deciding whether to revoke a registration the DA balances a number of open-ended factors with no requirement "to make findings as to all of the factors," and with power to "give each factor the weight [s]he deems appropriate." *Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Add *Chevron* deference to that mush and we have a very powerful Deputy Administrator. In other words, if in the future the DA were to find any errors in Novelty's records or operations (and, given that Novelty sells millions of doses a year, it is inevitable that she would), then she could revoke the registration by claiming a pattern of dangerous recordkeeping and distribution errors, knowing full well that Novelty would face an uphill scramble to persuade a court that she has abused her overflowing discretion. Given the law of large numbers, such a pattern could be found in *any* registrant's records, meaning *all* registrants live by the grace of the Deputy Administrator.

No, old-fashioned law will not save Novelty and the jobs of its employees. It does not matter that no Novelty executive has ever been convicted of a crime.

It does not matter that notwithstanding Novelty's millions of sales, the best evidence the DA can point to of diversion is one – *one!* – instance from over six years ago. It does not matter that the DEA inspected Novelty's records for years and never peeped about a problem before deciding to bring down the full weight of the Executive Branch on Novelty's head. It also is irrelevant that Novelty has credibly offered to overhaul its internal processes to comply with the DA's whims. When an agency has gone rogue, and when judicial review is gutted, the only thing left is the Law of the Jungle, the weak versus the strong. And in this war of all against all, who can withstand the might of the federal government?

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08-33]

Novelty Distributors, Inc.; Revocation of Registration

On January 17, 2008, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Novelty Distributors, Inc. (Respondent), of Greenfield, Indiana. The Order immediately suspended and proposed the revocation of Respondent's DEA Certificate of Registration, 003563NSY, as a distributor of the list I chemicals ephedrine and pseudoephedrine, on the grounds that its "continued registration is inconsistent with the public interest," and "constitute[d] an imminent danger to public health and safety." Show Cause Order at 1 (ALJ EX. 1) (citing 21 U.S.C. 823(h), 824(a)(4), and 824(d)).

More specifically, the Show Cause Order alleged that Respondent was storing listed chemical products at, and distributing them from, over 100 unregistered locations throughout the United States, in violation of Federal law and regulations. *Id.* (citing 21 U.S.C. 822(e), 21 CFR 1309.21 and 1309.23(a)).

Next, the Show Cause Order alleged that Respondent was distributing quantities of listed

chemical products "to small retail outlets such as convenience stores" in amounts "far exceed[ing] what those retail outlets could be expected to sell for legitimate, therapeutic purposes." *Id.* at 2. The Order thus alleged that the "listed chemical products distributed by [Respondent] in large quantities have been, and are likely to continue being, diverted to the clandestine manufacture of methamphetamine." *Id.* (citing cases). Relatedly, the Show Cause Order alleged that some "[s]mall retail outlets that receive large quantities of * * * listed chemical products from [Respondent] sell such products to individuals in amounts that cannot be attributed to legitimate individual needs," that "some of the retail outlets allow customers to make multiple purchases of scheduled listed chemical products within a single week, and in some cases, within a single day," and that "[s]ome customers of these retail outlets purchased more than 9 grams of ephedrine or pseudoephedrine base within 30 days in violation of 21 U.S.C. 844(a)." *Id.*[1]

The Show Cause Order further alleged that between January 1, 2007, and July 9, 2007, Respondent distributed listed chemical products "on at least 284 occasions to 35 retail outlets," which had not self-certified as required under Federal law. *Id.* (citing 21

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[1] The Show Cause Order also alleged that "[i]n November 2002, 22 bottles of ephedrine products distributed by Novelty were found at an illicit methamphetamine laboratory in Connecticut." Show Cause Order at 2.

U.S.C. 830(e)(1)(A)(vii)). *Id.* Moreover, on three occasions subsequent to February 1, 2007, Respondent allegedly distributed 24-count bottles of listed chemical products to retailers in violation of Federal law, which [sic] effective April 9, 2006, required that non-liquid form products be sold only in blister packs. *Id.* at 2-3 (citing 21 U.S.C. 830(d)(2)). Relatedly, the Show Cause Order alleged that Respondent had distributed tablet-form products to retailers in Kentucky and North Carolina in violation of the laws of these States which "prohibit the sale of non-liquid ephedrine and pseudoephedrine except in a gel-cap product." *Id.* at 3.

Finally, the Show Cause Order alleged that in July 2007, DEA had audited twenty listed chemical products which Respondent distributed. *Id.* at 2. The Show Cause Order alleged that Respondent "could not account for more than 60,000 dosage units of two ephedrine products" and that it also had "overages for 16 different * * * listed chemical products." *Id.* The Order thus alleged that Respondent "failed to maintain accurate records of its distributions and receipts of * * * listed chemical products in violation of 21 U.S.C. 830(a) and 21 CFR 1310.04." *Id.*

Based on the above allegations, I made the preliminary finding that the listed chemical products Respondent was distributing had been, and were "likely to continue to be, diverted into the illicit manufacture of methamphetamine." *Id.* at 3. I also found that Respondent's "failure to maintain effective controls against diversion, including its distribution

of large amounts of * * * listed chemical products that far exceed legitimate demand, contribute to the illicit manufacture of methamphetamine." *Id.* I thus came to the "preliminary conclusion that [Respondent's] continued registration during the pendency of these proceedings would constitute an imminent danger to the public health and safety," and immediately suspended its registration. *Id.*

On February 26, 2008, Respondent requested a hearing on the allegations. ALJ Ex. 2. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who proceeded to conduct pre-hearing procedures. A hearing was held on March 24 through March 28, and March 31 through April 2, 2008, at which both parties put on extensive testimony and introduced numerous documents into evidence.

Moreover, on March 24, 2008, Respondent filed an interlocutory appeal in which it challenged the ALJ's denial of its motion to remove one of the Government's lawyers from participating in the hearing, on the ground that he was a necessary and indispensable witness to the events surrounding the execution of an administrative search warrant which was the subject of its motion to suppress. *See* ALJ Exs. 12 and 13. On March 25, 2008, I denied Respondent's appeal on multiple grounds.[2] ALJ Ex. 13.

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[2] The grounds included that Respondent had not established that the Government's lawyer was a necessary and indispensable witness, and that Respondent had not cited a

(Continued on following page)

Following the hearing, both parties submitted briefs containing their proposed findings, conclusions of law, and argument. On May 21, 2008, the ALJ issued her recommended decision (hereinafter, ALJ).[3]

In her decision, the ALJ found that the Government's evidence regarding the monthly expected sales of combination ephedrine products at convenience stores ($14.39) to meet legitimate demand was "flawed and not credible." ALJ at 97. Relatedly, while acknowledging that "Respondent sells an approximate monthly average of $640.00 in SLC products to its convenience store customers," the ALJ observed that "there is no legitimate sales figure in the record" by which the excessiveness of its sales (and the likelihood that the products were being diverted) could be judged. *Id.*

Regarding the allegation that Respondent failed to maintain accurate records of its receipts and distributions, the ALJ concluded that the evidence pertaining to the audit did not establish "preponderating evidence either way to assist in analyzing

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single case to support its contention that the conduct of the Government lawyer – even if true – was a violation of its constitutional rights. Denial of Interlocutory Appeal, at 2-3 (ALJ Ex. 13.) I also noted that the Agency had previously held that the exclusionary rule does not apply to proceedings under 21 U.S.C. 824, and that the Supreme Court had "repeatedly declined to extend the exclusionary rule to proceedings other than criminal trials." *Id.* (quoting *Pennsylvania Bd. of Probation v. Scott*, 524 U.S.C. 357, 363 (1998)).

[3] The decision was 165 pages in length.

the accuracy of * * * Respondent's handling" of listed chemical products. *Id.* at 88. The ALJ concluded, however, that "Respondent's recordkeeping is not adequate to conduct an effective audit of its SLC products." *Id.*

The ALJ also rejected the allegation that Respondent had made numerous distributions to uncertified retailers based on testimony and documentary evidence that one of Respondent's officials had confirmed that these "customers were, in fact, self-certified." *Id.* at 91. The ALJ further found unproven the allegation that Respondent had thrice distributed listed chemical products in bottles in violation of Federal law, noting that Respondent had provided "documentary proof that the * * * product * * * had not been illegally distributed." *Id.* at 86. The ALJ also found unproven the Government's allegation that Respondent had distributed tablet-form products to retailers in Kentucky and North Carolina, noting that "Respondent produced credible testimonial evidence to support a finding that these illegal sales in fact did not happen." *Id.*

With respect to the allegation that Respondent was violating Federal law because it was distributing from over 100 drop-off points which were not registered, the ALJ noted that Respondent had challenged the Agency's interpretation in Federal District Court. *Id.* at 90-91. The ALJ found, however, that Respondent had been advised by a DEA Group Supervisor (GS) that its practice of shipping SLCs to numerous storage units which were not registered was illegal,

that it had continued [sic] do so without even seeking clarification from the Agency, and that this conduct was "not consistent with the requirements for a participant in a regulated industry." *Id.* at 91. However, because Respondent's declaratory judgment action was still "pending in federal court," the ALJ "conclude[d] that [the district court was] the proper venue for this issue" and declined to address the statutory question.[4] *Id.* at 91 n.38.

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[4] On August 7, 2008, the District Court granted the Government's motion for summary judgment and denied Respondent's cross-motion for summary judgment. *See* Entry on Cross Motions for Summary Judgment, *Novelty, Inc., v. Tandy,* No. 1:04-cv-1502-DFH-TAB (S.D. Ind., Aug. 7, 2008). Notably, the District Court held that the instructions in the Group Supervisor's letter were interpretive and not legislative rules, and were thus not subject to notice and comment rulemaking under 5 U.S.C. 553. *Id.* at 2. Pursuant to 5 U.S.C. 556(e), I take official notice of the District Court's decision. I also take official notice of the August 13, 2008 letter submitted by Respondent's President. In his letter, Respondent's President stated that he has ordered a change to Respondent's distribution practices and "reiterates its previously stated commitment to cooperate with [this Agency] and adhere to all conditions specified by [me] for [its] continued registration," Letter of Todd Green (Aug. 13, 2008).

In his letter, Respondent's CEO does not state that Respondent's will waive its right to appeal the District Court's decision. Moreover, I conclude that in light of the extensive resources that have been devoted to litigating the issue of the lawfulness of Respondent's use of unregistered locations to store and distribute SLCs, as well as the importance of the issue to the regulated industry, the issue should be decided.

Finally, the ALJ also found that following the suspension order, Respondent had attempted to enter into an agreement with one of its suppliers (BDI), under which its salespersons would still take orders for SLCs which would be shipped by BDI. ALJ at 92. Here again, the ALJ noted that there was no evidence that Respondent had asked the Agency if the arrangement was lawful. *Id.*

The ALJ nonetheless concluded that Respondent had "demonstrated a willingness to comply with the laws and regulations governing the distribution of SLC products," specifically noting that it had developed a training program for its customers, had provided them with the logbooks required by the CMEA, and lockable display cases for its products, and had upgraded its computer system. *Id.* at 98-99. The ALJ also noted that following the implementation of the CMEA, Respondent had "acted to remove * * * non-complying SLC products from its customers' shelves and [to] properly dispose of" them. *Id.* at 99.

With respect to the audits, the ALJ observed that while they "appeare[d] to reveal significant overages and shortages," Respondent had "credibly and adequately minimized those figures to a more acceptable margin of inventory error after analyzing its records and making its own audit findings." *Id.* Finally, while the ALJ noted that Respondent's continued distributions to the drop-off points "cause[s] concern," she further reasoned that except for the Group Supervisor's letter, it "had no notice from the [Agency] of any violations until the * * * Suspension Order was

served" on it, and that it "ha[d] not been given an opportunity to remedy the flaws identified by the Agency [in] this action." *Id.* at 100. Based on what she characterized as its "history of," and "financial commitment to," compliance, the ALJ reasoned that revocation would not be an appropriate sanction. *Id.* at 100-01. Instead, the ALJ recommended that I impose compliance requirements on Respondent to ensure that it operated in the public interest. *Id.* at 101.

Thereafter, the Government filed exceptions to the ALJ's decision. Respondent likewise filed a 140 page brief which supported the ALJ's decision while also excepting to certain findings and conclusions.

Having considered the entire record in this matter and all of the issues raised in the parties' exceptions, I hereby issue this Decision and Final Order. More specifically, I reject the allegations that Respondent distributed SLC products in violation of the CMEA and the laws of Kentucky and North Carolina as unsupported by substantial evidence. With respect to the allegations that Respondent engaged in 284 distributions to uncertified retailers, I conclude that the evidence establishes only a single instance of distributing to an uncertified retailer and several instances of inaccurate recordkeeping in that Respondent's records of the addresses for several stores did not match the actual addresses of the stores, and that the Government has not proved by substantial evidence that the stores were uncertified on the date of the distributions.

With respect to the audit, I conclude that because the ALJ found credible the testimony of one of Respondent's executives that the Agency's investigators had excluded certain transactions and inventory adjustments which it had provided to them, and the Government offered no rebuttal evidence, the allegation that Respondent had shortages and overages of various products is not proved. I find, however, that the evidence shows that Respondent's recordkeeping did not comply with federal law because it failed to maintain proper records of regulated transactions as required by Federal law and DEA regulations. *See* 21 U.S.C. 830(a); 21 CFR 1310.03, *id.* 1310.04, *id.* 1310.06. Because of this, as well as evidence showing that Respondent's list of shipments included three shipments of a product with a date of July 16, 2007, even though it was then only July 9, 2007, I find that Respondent does not have adequate systems for monitoring the receipt and distribution of SLCs. 21 CFR 1309.71(b).

With respect to the allegation that Respondent's sales of SLC were excessive and consistent with diversion, I agree with the ALJ that the Government's figure as to the expected monthly sales range is not supported by substantial evidence. I nonetheless conclude that Respondent does not maintain effective controls against diversion because its own evidence shows that it distributed SLCs to numerous stores in quantities that dwarfed what its average customer purchases, and that it did so even when it had previously developed concerns that a store was purchasing

excessive quantities, and that it does not even enforce its own sales limit policies.

Next, in contrast to the ALJ, I conclude that this proceeding is the appropriate forum to address the meaning of 21 U.S.C. 822(e) and the allegation that Respondent has repeatedly violated Federal law by distributing from unregistered locations. Consistent with the statutory text and purpose, I conclude that Respondent's practice of using unregistered self-storage units to store and distribute SLC products violated the Controlled Substances Act and DEA's regulation.

Finally, for reasons set forth below, I reject the ALJ's recommended sanction that Respondent's registration be continued with conditions. As explained below, because Respondent repeatedly violated Federal law notwithstanding that it was advised that its use of the unregistered self-storage facilities was unlawful, does not even enforce its own policies with respect to limiting sales, and attempted to circumvent the suspension order. I conclude that revocation is necessary to protect the public interest. I make the following findings of fact.

Findings

Respondent is a corporation which is solely owned by its President, Mr. Todd Green. Respondent is a wholesale distributor of various sundry items to between 10,000 and 12,000 convenience stores throughout the United States.

Since 1998, Respondent has held DEA Certificate of Registration, #003563NSY, which authorizes it to distribute pseudoephedrine and ephedrine from its registered location of 351 W. Muskegon Drive, Greenfield, Indiana. GX 1. Respondent's registration expires on October 31, 2008. *Id.*

Both ephedrine and pseudoephedrine have FDA approved therapeutic uses. GX 19, at 3. Ephedrine is lawfully marketed under the Food, Drug, and Cosmetic Act for OTC use as a bronchodilator to treat asthma,[5] and pseudoephedrine is lawfully marketed for OTC use as a decongestant. *Id.* at 3-4. Both substances are, however, regulated as schedule listed chemicals under the Controlled Substances Act because they are precursor chemicals which are frequently diverted into the illicit manufacture of methamphetamine, a schedule II controlled substance, a potent and highly addictive central nervous system stimulant. *See* 21 U.S.C. 802(34); *id.* 812(c); 21 CFR 1308.12(d). Moreover, in the course of investigating

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[5] The FDA has, however, issued a notice of proposed rulemaking which would remove combination ephedrine-guaifenesin products from the OTC monograph on the grounds that they are not "safe and effective for continued OTC availability." 70 FR 40232 (2005).

The parties also extensively litigated the medical appropriateness of using combination ephedrine products to treat asthma. *See* ALJ 43-48. I find it unnecessary to make any findings on this issue as until the FDA issues a final rule, combination ephedrine-guaifenesin products can be lawfully marketed for this purpose.

methamphetamine trafficking, DEA has frequently found that the listed chemicals which are used by smaller illicit labs have been sold by convenience stores, gas stations, and other small retailers. GX 51, at 56, 59, 62, 66; GX 54, at 29-30.[6] *See also TNT*

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[6] Based on the testimony of a witness whose experience was limited to the Shenandoah, Virginia valley, the ALJ found that the street price of a gram of methamphetamine is "between $20.00 and $50.00 per gram." ALJ at 48-49. Based on this, as well as evidence regarding the yield and conversion rate, the ALJ found that "it would cost a methamphetamine cook between $50.00 and $144.00 to produce 1 gram of methamphetamine," ALJ at 50. The ALJ thus concluded that "using the Respondent's product to manufacture methamphetamine makes little monetary sense." *Id.* at 96.

I reject the ALJ's finding regarding the street price of methamphetamine and her conclusion that using Respondent's product "makes little monetary sense." *Id.* As for her findings regarding the street price of methamphetamine, I note that it is based on anecdotal evidence and limited to a small region of the State of Virginia. Respondent does not, however, limit its distribution of SLCs to this region of the country. I further note that it runs counter to the data which this Agency obtains on a periodic basis, and which show that in most of the country, methamphetamine prices are substantially higher than they are in the Shenandoah Valley. *See* U.S. Dep't of Justice, *National Illicit Drug Prices – December 2007,* 32-37 (Mar. 2008). In accordance with 5 U.S.C. 556(e), and 21 CFR 1316.59(e), I take official notice of the methamphetamine street price data contained in this publication. Moreover, the ALJ's conclusion assumes that methamphetamine addicts engage in economically rational behavior. There is, however, no evidence in the record to support this assumption. I therefore reject the ALJ's conclusion.

I also find 'that this witness's testimony that convenience stores are not the source of precursors in the Shenandoah Valley

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Distributors, 70 FR 12729, 12730 (2005) (noting testimony of Special Agent that "80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores").

Prior to the suspension of its registration, Respondent sold combination ephedrine and pseudoephedrine products under the brand names of Double Action, Mini, and Ephedrine Plus in package sizes of two, six, twelve and twenty-four count. Tr. 561, 692-93. Respondent sold these products to approximately 3,500 to 4,000 convenience stores in approximately thirty different States. *Id.* at 80-82, 558-60, Respondent does not carry any other OTC drug products. *Id.* at 552.

Respondent employs approximately 150 sales persons, who typically visit each store every other week.[7] Tr. 2046, 1290. Using its own tractor-trailers, Respondent ships products including SLCs from its Greenfield warehouse to each sales person's "drop-off point," which is a unit in a commercial self-storage facility. *Id.* at 73-75. According to the testimony of Respondent's owner and CEO, Respondent was using approximately 150 to 180 drop-off points at the time the immediate suspension was served on it. *Id.* at 76.

(ALJ at 49), to be anecdotal and contrary to the Agency's experience throughout the country, I thus give it no weight.

[7] Approximately 90% of the stores are on this schedule; the remaining stores are visited either weekly or monthly. Tr. 1290.

Both the driver who delivers the product to the drop-off point and the route sales person have keys to the storage unit. *Id.* While the sales persons are notified of each arriving shipment, SLCs can sit in the storage units for several days before the sales person retrieves them for delivery to the stores.[8] *Id.* at 534, 668. Moreover, according to one of Respondent's

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[8] It is undisputed that the SLCs are not shipped back to Respondent's registered location prior to their being distributed.

At the hearing, an executive of Respondent insisted that "we are not storing product in * * * unregistered locations," and added: "Now your coming back into the definition of what is storage. We're not storing the product in that location," referring to the drop-off points. Tr. 666-67. *See also id.* at 668 ("We're not storing or keeping or whatever words you want to try and use, product in these warehouses, against the law. We're not doing it."). The executive acknowledged, however, that products may stay in the storage units for "a few days." *Id.* at 667. I therefore find that Respondent is storing products in the self-storage units.

Respondent further asserted that its distribution system provided more security than shipping the products via such common carriers as UPS or Fed Ex. *See* Tr. 644-45. Yet an executive of Respondent acknowledged that it uses temporary drivers on a contract basis. *Id.* at 693, 697. Relatedly, Respondent's CEO offered testimony as to perceived security inadequacies at UPS, asserting that "[p]roduct delivered by UPS could easily be stolen anywhere in the system." *Id.* at 157.

On cross-examination, however, Respondent's CEO admitted that he had not taken a tour of a UPS facility, *Id.* at 161. When asked when he had last "checked into the training that UPS personnel have with regard to handling [SLCs]?," he answered: "I assume they don't have any training, since they're not DEA regulated facilities," *Id.* at 162. The ALJ did not address the credibility of the CEO's testimony. As ultimate factfinder, I reject it as lacking foundation.

executives, the SLCs can remain on the salesperson's truck for up to nine days depending upon the demand for the product. *Id.* at 1282, 1421.

None of the drop-off points is registered with the Agency. Tr. 1284. Moreover, the units do not have separate cages for storing SLCs, *id.* at 132, and the facilities have varying degrees of external security with some having cameras and requiring access codes while others have no additional security. *Compare id.* at 131, *with id.* at 538 (former salesperson testifying that anyone could come off the road and access the door and padlock to his route storage unit).[9] Moreover, DEA Investigators could not determine the addresses of thirty-four of the drop-off points. Tr. 1196-98.[10]

In a letter dated May 5, 2004, the Diversion Group Supervisor of the Indianapolis, Indiana DEA District Office, advised Respondent that "any storage at, and distribution from, a location other than the

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[9] There is no dispute that the security at Respondent's Greenfield warehouse is adequate. It is also undisputed that following the enactment of the CMEA, Respondent prepared a training video for its customers and supplied them with logbooks and cases for storing SLC products. Tr. 1390 & 1422; RXs 34, 47, & 48.

[10] On its list of shipments, Respondent used code numbers to indicate where products were being shipped to. Tr. 1196. Moreover, Respondent initially refused to turn over information identifying the addresses of the drop-off points for the sales routes, claiming that it was outside the scope of the warrant. *Id.* at 1197.

registered location (including the use of delivery vehicles for overnight storage) is a violation of federal law."[11] GX 100. Upon review of the letter, Respondent sought a declaratory judgment in Federal District Court challenging the interpretation set forth in the letter. Tr. 652-53. At no time, however, did Respondent change its practice of distributing to the drop-off points. *Id.* at 664-65. Nor did Respondent seek a review of the letter by officials at the Agency's headquarters, ALJ at 18.

The record further establishes that at the time the listed chemical products are shipped from its Greenfield, Indiana warehouse (which is its only registered location) to the drop-off points, the products have not been sold to a particular store. Tr. 2079. Indeed, the amount of SLCs to be sold to a customer is not known until the route sales person visits the store and determines how much product the store

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[11] The letter also reviewed three scenarios "in case [Respondent was] storing List I chemical products * * * and distributing them from satellite locations, such as commercial storage units, personal residences and or delivery vehicles," GX 100, at 1. The first two scenarios involved sales representatives who picked up listed chemicals from a registered location either to fill a preplaced order or a "general order," and could not return the products "to the registered location at the end of the day." *Id.*

The third scenario was "a company [that] ships orders containing List I chemicals to sales representatives at remote locations." *Id.* at 2. The letter further explained that "DEA considers this to be freight forwarding and at this time * * * has no provisions that would permit freight forwarding for List I chemical products." *Id.*

needs. *Id.* at 1282. The sales person counts the product on hand, discusses the order with the store manager, and restocks the store. *Id.* at 631; 1422.

Moreover, at the time an SLC order is placed, only the salesperson – and no one at Respondent's headquarters – knows how much the store has purchased. *Id.* at 633. The salesperson is required to enter the order information into a handheld computer which generates an invoice; this information is later transmitted back to Respondent's headquarters. *Id.* at 634. The salesperson is also required to return a paper copy of the invoice, as well as a shipping document which accompanies the delivery of the SLCs from the warehouse, to headquarters. *Id.* at 688. Under its system, while Respondent's headquarters can determine which salesperson has received product with a particular lot number, it cannot identify the specific store that obtained a particular lot number of a product. *Id.* at 1517.

Respondent's CEO testified that a store could purchase up to a case of an SLC product in each "service cycle,"[12] *Id.* at 101. Accordingly, most stores could purchase two cases per month of each product. Moreover, Respondent sold more than ten different SLC products. *Id.* at 623.

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[12] With respect to the 24-tablet products, the record establishes that there were 144 packages in a case. Tr. 621. The record does not, however, establish how many packages there were in a case of the smaller size packages. *Id.* at 624.

According to one of its executives, the company monitors the sales of each SLC product at each store throughout the week to determine whether a store "is increasing [its] inventory more than [Respondent] expects [it] to," and if it is, the company contacts the salesperson to inquire further. *Id.* at 2061-62. This executive also asserted that in this event, it would send in one of the salesperson's supervisors to visit with the sales person and determine the true inventory at a store. *Id.* Moreover, another executive claimed that he "receive[s] a computer-generated report indicating any time that more than one case has been sold to a single retail location of a single" product and issues a warning letter to its salespersons. *Id.* at 1431. Respondent's CEO and Owner further testified that if a customer obtained more than a case of a product, he "would cut them off, [and] stop the sale of product to them."[13] Tr. 159. *See also* RX 10, at 1 (asserting that stores purchasing "unusual quantities" would be "monitored over the following 4 week period," and that "[i]f further unusual activity is noted," Respondent "will discontinue sales of all or part of the List I products sold to the store").

According to one of Respondent's executives, between January 17, 2007 and January 17, 2008, that

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[13] While the ALJ credited the CEO's testimony, the e-mails discussed in note 14 below, show otherwise. *See, e.g.*, RX 56, at 3. Moreover, Respondent did not identify a single store which it had refused to sell SLCs to.

there had been "approximately 35 to 45" violations of the one case limit, and most of the violations had occurred before July 2007, when the Agency executed the administrative warrant. *Id.* at 1433. The ALJ, however, credited the testimony of a DEA DI who reviewed Respondent's sales records for the period between January and July 2007, and found that its salespersons exceeded the one case limit 85 times. Tr. 1496-1506; GX 68.

The same executive stated that Respondent had only started issuing written warnings to its salespersons after August 2007 because of a computer "glitch" which had resulted in the reports not being issued as scheduled. *Id.* at 1435. Moreover, while Respondent introduced into evidence a few e-mails indicating that the company had cut off supplying 100-count bottles to several stores, Respondent did not identify a single store to which it had refused to sell ephedrine.[14] Indeed, according to its own evidence, one of the stores (BPM55), which it had

[14] The record contains several e-mails indicating that Respondent directed its employees to not sell 100 count ephedrine to several stores. *See* RX 56. While the e-mails expressed concerns about the excessiveness of these stores' sales of ephedrine products, notably, Respondent did not cut off all sales of the products to any of the stores. *See id.* Moreover, while it restricted its sales "to a maximum of [one case] every 2 weeks" and prohibited the sale of 100 count ephedrine to store number BPM55, this store was its leading SLC customer in the three months prior to the issuance of the suspension order, during which it purchased products with an average of retail value of $7317.77 per month. *Compare* RX 56, at 1, *with* RX 27A, at 1.

previously stopped selling 100-count products to because of its excessive purchases, was allowed to purchase products with a retail value of more than $7300 a month, in the three months prior to the issuance of the suspension order. *Compare* RX 56, at 1, *with* RX 27a, at 1.

According to one of its executives, Respondent's SLC customers purchased SLCs with an average retail sales value of $640 per month, with the majority of the products containing ephedrine. *Id.* at 563-64, Moreover, according to one of Respondent's exhibits, in the three months prior to the issuance of the suspension order, it distributed listed chemicals products with an average monthly retail sales value greater than $2000 to approximately 120 of its customers. RX 27A. Respondent also distributed listed chemical products with an average monthly retail sales value in excess of $3000 to thirty-four customers, and product with average monthly retail sale value greater than $4000 to nine customers. *Id.* Finally, Respondent distributed to its two largest customers, products with an average monthly retail sales value of $5056 and $7314 respectively. *Id.*

At the hearing, the Government put forward expert testimony to the effect that the expected sales range of ephedrine products at convenience stores to meet legitimate demand was $14.39 per month. GX 25, at 8. In his declaration, the Government's expert stated that U.S. Economic Census data show that only about 31.5% of all convenience stores (45,077 stores) carry non-prescription drug products. GX 99,

at 7. According to his declaration, the Government's expert then applied "these statistics" to the National Association of Convenience Stores 2007 Survey revenue data which show that convenience stores sold a total of $292,000,000 of cough and cold remedies during 2006, to calculate the annual and monthly average sale of cough and cold products at a convenience store. *Id.* According to the Government's expert, stores carrying the HBC line had average annual sales of all cough and cold products of $4,080.18, and average monthly sales of $340.01. *Id.*; *see also id.* at Table 2.

The Government's expert did not explain, however, why he used the total number of stores carrying the HBC line[15] (71,565 stores) rather than the smaller number of stores that he had determined carried non-prescription drug products (45,077 stores). *See id.* at Table 2. Moreover, the Government did not rebut the testimony of Respondent's expert that because of legislation in twelve States, convenience stores can no longer sell ephedrine products and that the stores in these States comprise 23% of the nation's convenience stores. RX 59, at 10. This suggests that at most,

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[15] The HBC line includes analgesics, stomach remedies, vitamins, other OTC drugs, grooming aids, feminine hygiene, family planning, baby care, skin care, cosmetics, and some other unspecified products.

34,709 convenience stores nationwide carry ephedrine products. *Id.*[16]

Next, the Government's expert determined the percentage of cough and cold remedies comprised of ephedrine products. GX 99, at 8. According to the Government's expert, "[t]his factor was derived from a tabulation of MRI data showing asthma remedy usage by retail channel (in this case, convenience stores)." *Id.* Based on this data, which was included at Table 1, the Government's expert concluded that ephedrine products constitute 8.36% of cough and cold remedies sold at convenience stores. *Id.* Multiplying this figure times the average monthly total sales of cough and cold products, the Government's expert concluded that the average monthly sale of all ephedrine products at convenience stores selling the products was $28.43.[17] *Id.*

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[16] Respondent's expert also pointed out that some convenience stores that carry non-prescription drug products may not sell any ephedrine. RX 59, at 10.

[17] As part of its case, the Government entered into evidence a declaration prepared by its expert in another matter. *See* GX 25. In this document, the expert stated that he had also looked at data which included "cumulated observed transactions," such as scanner data obtained by Information Resources, Inc. *Id.* at 7. The Government's expert also testified that in preparing GX 25, he had reviewed scanner data to determine "the proportion of the nonprescription drug category that included preparations for the treatment of asthma containing ephedrine." Tr. 313 & 500. However, in his rebuttal declaration, the Government's expert made no mention of having used scanner data. *See* GX 99.

Respondent's expert stated, however, that the MRI Survey (which is a survey of 50,000 consumers) does not provide sufficient information to support the Government's expert's figure that ephedrine products constitute 8.36% of cough and cold remedies sold at convenience stores, RX 59, at 11. Respondent's expert noted that the MRI Survey (which was included as an attachment to RX 59) "reports absolutely no information about any ephedrine products," and "reports absolutely no information on whether consumers bought either an asthma remedy or a cough and cold remedy from convenience stores." *Id.* (emphasis deleted).

Respondent's expert further opined that the MRI Survey asks three questions which "are inadequate to form an estimate" of the percentage of cough and cold remedies constituting ephedrine, RX 59, at 11. The first question is: "How many times in" various time periods has the person used one of numerous products? *See Survey of the American Consumer* 2-106. While the survey includes a list of non-prescription cold, sinus, and allergy remedies, none of the products listed contain ephedrine. *Survey* at 12. Nor does it appear that an ephedrine product is listed anywhere in the survey.

As for the remaining two questions, the survey asks whether a person has had asthma in the last twelve months, and whether they have used a prescription drug, a non-prescription drug, an herbal remedy, or have not treated the condition at all. *Id.* at 15. The survey does not ask any further questions

regarding the use of non-prescription drugs to treat asthma.

Finally, with respect to the use of convenience stores, the survey asks only whether the consumer has purchased a non-prescription/OTC drug at a convenience store in the last 30 days. *Id.* at 43. Again, the survey does not inquire further as to what type of drug the consumer may have purchased at a convenience store. The Government's expert did not explain how the data obtained in the answers to these questions supported his conclusion that ephedrine products constitute 8.36% of the cough and cold remedies purchased at convenience stores.[18]

The Government's expert further stated that he used "[a]nother MRI tabulation showing the route of the drug (powder, tablet, liquid, mist, skin patch, etc., etc.), [which] enabled the estimate to be further adjusted to reflect tablets only * * * resulting in the final estimate of $14.78." *Id.* The Government's expert thus concluded that 52% of ephedrine users use tablets rather than inhalers, *id.* at Table 2; multiplying this figure times the average monthly sales of

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[18] Respondent's expert noted that she was informed by its executives that ephedrine products constituted 60% of its customers' SLC sales. RX 59, at 12. Even if this is an accurate figure with respect to its customers, Respondent does not allow them to purchase SLCs from other suppliers, Tr. 626-27, and it does not sell any nationally-branded OTC pseudoephedrine remedies such as Sudafed or Claritin D. The figure is thus based on a biased sample.

$28.43, the expert concluded that the average monthly sale of tablet-form ephedrine products at convenience stores was $14.78. *Id.* at 8.[19]

The MRI survey asks, however, only about the mode of administration with respect to cold, sinus and allergy remedies and not asthma remedies. *Survey,* at 12. Here again, it is unclear why this data provides a reliable basis for estimating the percentage of asthma sufferers who use tablets versus inhalers.

I thus agree with the ALJ that the Government has not proved by substantial evidence that the monthly expected retail sales value of ephedrine products at convenience stores to meet legitimate demand is $14.39.[20] On the other hand, it is undisputed

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[19] Because the average retail price for a box of the two loading brands of ephedrine was $7.19, the Government's expert then further reduced the average monthly sales figure from $14.78 to $14.39 "to reflect the purchase of exactly two boxes of 24 count ephedrine tablets," *Id.* at 9.

[20] The Government offered evidence regarding visits or telephone contacts made by various Diversion Investigators (DIs) to eighteen pharmacies which were apparently located near some of Respondent's customers. *See* ALJ Doc. at 23-33. At least half the pharmacies did not carry any ephedrine products. *See id.* As for the remaining pharmacies, the Government produced evidence as to their sales levels of ephedrine products with respect to only four of the pharmacies. This evidence showed that the pharmacies were selling minimal quantities of tablet-form ephedrine products, with the most that any store sold being 71 boxes in a four-and-a-half month period. *See, e.g.,* GXs 26, 27, 28 & 29.

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that no ephedrine product ranks in the top 200 of over-the-counter and health-and-beauty care products which are sold in drug stores, supermarkets, and mass merchandisers. *See* GX 99, at 4, It is also undisputed that approximately 97% of the sales of non-prescription drugs occurs at pharmacies, supermarkets, warehouse clubs, department stores, electronic shopping/mail order houses, and other general merchandise stores. GX 25A, at C2. Moreover, convenience stores (both those with and without gasoline) account for approximately 1.14% of the total commerce in non-prescription drugs. *Id.* The Government, however, produced no evidence as to the annual sales of combination ephedrine products such as Primatene Tablets and Bronkaid, which are sold at pharmacies, supermarkets, and other large volume retailers of non-prescription drugs.

Evidence of Diversion

In September 2002, DMD Pharmaceuticals, a supplier to Respondent, shipped it an entire lot of sixty-count bottles of a combination ephedrine (25

The Government did not establish that it used a statistically valid sampling technique in choosing the pharmacies the DIs interviewed. The evidence thus amounts to nothing more than a collection of anecdotes. To the extent the evidence is offered to show that there is little demand at pharmacies for these products, it is of limited probative value.

mg.) product.[21] Tr. 1079. Two months later, twenty-two bottles of this lot were found at an illicit methamphetamine laboratory in Thompson, Connecticut. *Id.* at 1077. DEA subsequently issued a warning letter to DMD. *Id.* at 1077-78.

Several months later, while completing a previously-commenced inspection of Respondent, a DI discussed the matter with two of its executives. *Id.* at 1082-83. While the executives provided the DI with the names of two salespersons whose territory included or was near the part of Connecticut where the lab was found, they could not identify which specific stores had obtained the ephedrine. *Id.* at 1084.

As part of the investigation that gave rise to this proceeding, DIs based in four States visited a number of Respondent's customers. At a Roadrunner Market in Bristol, Tennessee, a DI testified that during the "time period of July 23rd through August 23rd" of 2007, three customers had purchased quantities that far exceeded nine grams.[22] Tr. 730-733. While 439 gel

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[21] According to the testimony of a DI, DEA issued DMD a warning letter. Tr. 1078. Upon receipt of the letter, DMD's compliance manager told the DI that he would look into to whom the product was shipped. *Id.* Subsequently, the DI received a phone call from DMD's compliance manager and owner informing her that "that entire lot had been sold to" Respondent in September 2002. *Id.* at 1079. The ALJ credited this testimony, *see* ALJ at 13, as do I.

[22] It is noted that the time period which was reviewed exceeded thirty days. Even assuming that these persons did not

(Continued on following page)

caps in 25 mg. strength is the dosage form equivalent to the nine gram limit, M.W. had bought 56 boxes totaling 1,344 gel caps or approximately 27 grams. GX 46. During the same period, C.M. purchased 23 boxes totaling 552 gel caps (approximately 11.3 grams), and E.B. purchased 52 boxes totaling 1,248 gel caps or approximately 25.6 grams. *Id.* The DI also found other evidence of repetitive purchasing patterns at the stores, but the logbooks were missing information such as the number of dosage units and/or strength of the product. *See* GX 80.

A different DI visited the Smoker Friendly No. 4 Store in Little Falls, New York, and obtained the logbooks. Tr. 785-86, 791-92. The logbooks showed that between July 27, 2007, and August 27, 2007, four persons had purchased more than nine grams. K.S. bought 984 tablets of ephedrine 25 mg. (more than 20 grams), and A.P. bought 768 tablets of ephedrine 25 mg. (approximately 15.7 grams). GX 45. Moreover, Richard and Robert R., who had the same last name and used the same address, respectively purchased 600 and 696 tablets of ephedrine 25 mg. *Id.* These purchases amounted to 12.3 and 14.25 grams. *Id.*

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violate Federal law in purchasing these products, given the dosing instruction for these products (one tablet every four hours and no more than six tablets every twenty-four hours), their purchases are not consistent with the use of the products to treat asthma. *See, e.g.*, RX 9, at 1. Moreover, the "Drug Facts" warning label for Respondent's Double Action Ephedrine (25/200 mg.) product further advises to "Stop use and ask a doctor if * * * cough persists for more than 1 week," *Id.*

Another DI visited the Mason of New York convenience store of Jamestown, New York, and obtained the logbook. Tr. 1484. The logbook entries were frequently missing information as to the strength of the ephedrine tablets that had been purchased. Nonetheless, the logbook showed that there were five individuals who, even if they had purchased only 12.5 mg. ephedrine, had nonetheless purchased more than nine grams during the period between July 21 and August 21, 2007. More specifically, M.M. purchased 1,368 tablets (14 grams),[23] A.J. purchased 1,014 tablets (10.4 grams), J.B. purchased 1,548 tablets (15.9 grams), J.H. purchased 1,068 tablets (10.9 grams), and R.B. purchased 1,002 tablets (10.3 grams).[24] GX 49.

A Pennsylvania-based DI likewise found evidence of purchases that, while technically not in violation of the CMEA, raised a strong suspicion that the ephedrine was being diverted. For example, at the CoGo of Somerset, Pennsylvania, a DI found that S.M. had bought 384 dosage units between August 16 and 23, 2007. GX 75. At 12.5 mg. strength, this amounted to 3.9 grams. This individual had also bought three

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[23] A person named Chris M. (with the same last name and address as M.M.) purchased an additional 360 tablets. GX 49.

[24] All of these calculations assume that these persons bought 12.5 mg. tablets; if they bought 25 mg., then the amount of ephedrine was double. Moreover, the DI found that four other persons had purchased quantities which would exceed nine grams if the strength of the tablets was 25 mg.

twenty-four count boxes on three consecutive days.[25] *Id.* Moreover, another DI visited a CoGos in Midland, Pennsylvania, and found evidence that a person had bought 620 dosage units of 12.5 mg. between May 1 and May 31, 2007, and an additional 636 dosage units between June 1 and June 15, 2007. Tr. 1486; GX 41.

The Allegation That Respondent Distributed Listed Chemicals to Uncertified Retailers

Effective September 30, 2006, the CMEA prohibited a retailer from selling schedule listed chemical products unless the retailer had self-certified to the Attorney General that all "individuals who are responsible for delivering such products into the custody of purchasers or who deal directly with purchasers by obtaining payment for the products * * * have * * * undergone training provided by the seller to ensure that the individuals understand the requirements that apply" to the sale of the products. 21 U.S.C. 830(e)(1)(VII). As stated above, the Government alleged that between January 1, 2007, and July 9, 2007, Respondent made 284 distributions of listed chemical products to thirty-five retailers who were not self-certified.

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[25] At two stores, the DI did not find any evidence of purchases in excess of the limit and was told by the managers that the products were primarily purchased by hospital workers and truck drivers who used them to stay awake on their jobs. Tr. 872-73; 886-87.

As support for the allegation, a DEA DI testified that using a document supplied by Respondent which listed the customers by code number, store name and address, she conducted a spot check to see if the stores were listed in the Agency's database of stores that had become certified. Tr. 1213-19. The DI further testified that the results of her inquiry were reported in a thirteen page document, which listed the distributions by Respondent's store code number, the date, Respondent's product code, and quantity. *Id.* at 1218, *see also* GX 40 (listing stores and transactions).

At the hearing, Respondent produced numerous documents that refuted the allegation. For example, the Government listed twenty-five Speedway stores that were located in Indiana and Kentucky which had obtained SLCs from Respondent between April 10 and July 9, 2007. GX 40, at 3, 6 & 7. Respondent, however, introduced into evidence, a letter dated April 3, 2007 from an executive of Speedway Super America to DEA's registration unit submitting a CD-Rom with the certification data for the company's stores in Indiana and Kentucky. RX 57. Respondent also submitted copies of each store's certification. *See* RX 57A. While each of the certifications was dated July 5, 2007, the Government did not rebut Respondent's evidence that the Agency considers a chain retailer who submits information on a CD-Rom to be self-certified on the date the information is received by the Agency. Tr. 1335-36.

At most, the evidence suggests that Respondent made a single distribution to a single store before it

obtained its certification. *Compare* GX 40, at 14, *with* RX 57, at 18. According to these exhibits, Respondent distributed a listed chemical product on January 18, 2007, to an independent convenience store located in Centreville, Virginia, prior to the store obtaining certification on March 8, 2007.[26]

The evidence did show, however, several instances in which Respondent's records contained erroneous information. For example, Respondent's records listed the address of store XTM7480 as 1451 Dorsey Road, Hanover, Maryland. GX 39, at 100. The store's DEA Certificate states, however, that its address is 7500 Ridge Road, Hanover, MD. RX 57, at 14. Respondent's records likewise listed the address of store XTM7520 as 7300 Washington Blvd., Dorsey, MD. GX 39, at 100. According to its DEA certificate, the store's address was 7300 Washington Blvd, Elkridge, MD. RX 57, at 15. Also, Respondent's record listed the address of store MTO102 as 995 Old Airport Road, Bristol, TN. GX 39, at 33. The store's DEA certificate, however, gives its address as 1001 Airport Road, Bristol, Va. RX 57, at 16.[27]

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[26] The store's certification shows that it was completed online at DEA's self-certification Web page. RX 57, at 18.

[27] Likewise, Respondent's records list the address for store BGP1 as 1699 N. Dixie Hwy., Monroe Michigan. GX 39. The store's DEA certificate gives its address as 1488 N. Dixie Hwy., Monroe, Michigan. RX 57, at 21.

The Allegations That Respondent Distributed Products in Forms That Could Not Be Lawfully Sold Under the CMEA and State Laws

Effective April 9, 2006, the CMEA prohibited a retailer from selling a listed chemical "product in nonliquid form (including gel caps) at retail unless the product is packaged in blister packs * * * containing not more than 2 dosage units, or where the use of blister packs is technically infeasible, the product is packaged in unit dose packets or pouches." 21 U.S.C. 830(d)(2). The Government alleged that subsequent to February 1, 2007, Respondent distributed 24-count bottles of listed chemical product to retailers on three occasions.

In support of this allegation, the Government introduced a document which lists three distributions of Respondent's product # 17902, Mini 2 Way 25 mg. gel caps in 24 count bottles, to three stores (PTR3295, PTR3438, and PTR3973).[28] *See* GX 66 & 37. A DI testified that the three transactions were found in Respondent's sales records. Tr. 1442-45. According to Respondent's customer list, each of the stores was owned by The Pantry chain. *See* GX 39.

Respondent's record of shipments showed, however, that the product had not been shipped after

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[28] According to Respondent's sales records, two of the distributions (to stores PTR3295 and PTR3438) occurred on February 7, 2007; the other distribution (to store PTR3973) occurred on April 23, 2007. GX 66, Tr. 1442-43.

January 2006. RX 40, at 152. Moreover, Respondent presented e-mail correspondence between it and an employee of The Pantry. More specifically, Respondent requested that The Pantry check its scanner data to determine whether it had sold the bottled product at the three stores after February 1, 2007. RX 46, at 2-3. In an e-mail, a Pantry employee reported that she had checked the item number for the three stores "from Feb. 2007-Feb. 2008 and [that] there was no movement at any of the three locations for this item." RX 46, at 1.[29] Based on the totality of the evidence, I find that the Government has not proved this allegation.

The Government also alleged that Respondent distributed tablet-form products to retailers in Kentucky and North Carolina, after these States prohibited the sale of non-liquid products other than in gel-cap form at establishments that are not pharmacies. In support of the allegation, the Government introduced a document which listed four distributions of Respondent's product # 017550, Ephedrine Plus

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[29] Respondent's CEO attributed the data as resulting from its salesperson[s] having entered the wrong product code in their computer. Tr. 68. Another of Respondent's testified that that it had reprogrammed its computer system to prevent a salesperson from selling an item that was prohibited. *Id.* at 1404. Yet even after the reprogramming, there were several instances in which salespersons entered the codes for discontinued products. *Id.* at 1405. The same executive acknowledged that he did not know if the salespersons still had obsolete products in their storage units. *Id.*

Blister 24 Count. *See* GX 37 & 65. Three of the distributions were made to three stores owned by Circle K Midwest which were located in Kentucky (CKM 3212, CKM 3247, and CKM 3248); the other store was owned by The Pantry and located in North Carolina (PTR3972). *See* GX 39, at 10, 11 & 65. According to Respondent's records, the distributions occurred on March 27 and 28, and July 9, 2007.

An executive of Respondent testified that its records pertaining to the four distributions were erroneous. Tr. 1347-50. Moreover, Respondent's records did not show any shipments of this product after December 26, 2005. RX 40, at 159. Finally, in an e-mail, an employee of The Pantry reported that "there was no movement" of the product at store number 3972. RX 46, at 1.[30] Because the ALJ found credible Respondent's explanation and did not produce sufficient evidence to reject this finding, I find that Government has proved only that Respondent's records were erroneous and that it did not violate North Carolina or Kentucky law.

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[30] Respondent also submitted an e-mail from an employee of Circle K., which states that she checked the stores' sales going back to April 30, 2007, and that the stores had not sold the product. RX 46, at 5. The e-mail is thus not probative of whether Respondent distributed the products in violation of Kentucky law.

The DEA Audits

On July 9, 2007, as part of an administrative inspection of its registered location, DEA Investigators took a physical count of Respondent's listed chemical products then on hand. Tr. 1163. The DIs also obtained an initial inventory dated December 25, 2005, from Respondent's records. *Id.*; *see* GX 4. Both the beginning and ending inventories were certified as correct by Ryan Polk, Respondent's Chief Financial Officer. GX 4. Pursuant to an agreement with the DIs, products which were stored in the returns portion of Respondent's storage cage which included out-of-date products, broken blister packs, and single loose pills were not counted. Tr. 1494-95. The products had not, however, been logged back into Respondent's records. *Id.*

DEA Investigators audited twenty different products by adding Respondent's receipts (including returns. Tr. 1182) to the beginning inventory (GX 34)[31] and comparing this figure with the sum of the closing inventory and Respondent's shipments to its salespersons (GX 35) and returns to its suppliers. *See* GX 4, at 3. Of further note, Respondent's list of

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[31] According to the DI, the investigators "asked to see receipts for the products audited for a time period. And we were, instead, given this three-page summary." Tr. 1170. Relatedly, the DI testified that while Respondent gave them a 157 page list of its shipments, the document used product codes and the Investigators had to ask several times for a document which identified the products. *Id.* at 1180-81.

shipments indicated that it had made three separate shipments of product # 17121 (totaling more than 2300 units[32]) to three of its salespersons on July 16, 2007, notwithstanding that this date was a week into the future. GX 35, at 29.

According to the DIs' calculations, only one of the products in which there was activity balanced,[33] two of the products had sizable shortages, and the remaining had overages. *Id.* More specifically, the DI identified Respondent's product code #17902 (Mini 2-Way 25 mg. 24 count gel cap bottles) as being short nearly 28,000 bottles. Tr. 1186. Moreover, the DI concluded that Respondent was short 32,913 units of product code # 17903 (Mini 2 Way 12.5 mg. gel cap 6 ct, blister packs). *See* GX 4, at 3.

The DI further testified that "because we got different numbers when comparing [Respondent's] receipts versus their warehouse documentation," Tr. 1186, she conducted an additional audit of four products by obtaining information from Respondent's suppliers in order to verify its receipts. *Id.* at 1187. According to the DI, for these four products, there were substantial differences between the quantities that were reported by the suppliers and the information provided by Respondent. *Id.* With respect

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[32] This product was a six-count blister pack. *See* GX 32, at 1.

[33] While two other products balanced, the computation chart indicates that there was no beginning or closing inventory of, and no activity in, these products. GX 3, at 6.

to product # 17121 (Double Action 6 ct. ephedrine 25 mg. tablets), Respondent had represented that its receipts were 656,688, but according to the DI, the suppliers had claimed to have sold it only 429,024 units resulting in an overage of more than 275,000 units. Tr. 1188; GX 4, at 3. The DI also found overages in the other three products which were subject to the additional audit. GX 4, at 3. The DI further testified that she prepared an additional document which compared the receipt information provided on Respondent's printouts, the hard copy invoices of Respondent's receipts, and the quantities which the manufacturers of Respondent's products reported to the DI. Tr. 1189-90; GX 69.

According to this document, while Respondent's printout of its receipts for product #17103 (525,240 units of Double Action 12 ct. Blister 25 mg.) matched the quantity of the manufacturer's report, Respondent had no hard copy invoices. GX 69. With respect to product # 17131 (Double Action Pseudo tablets 12 mg.), Respondent's printout indicated it had received 404,184 units and the manufacturer reported that it had sold 403,248 units to Respondent. *Id.* Respondent did not, however, have any hard copy invoices for the product. *Id.* With respect to product # 17121 (Double Action 6 ct, ephedrine 25 mg.), Respondent's receipts (656,688 units) matched the number reported by the manufacturer. *Id.* Respondent, however, had hard copy invoices for only 429,024 units. *Id.*

With respect to product # 17125, Respondent's printout indicated it had received 1,011,901 units,

which matched the total quantity reported by the two suppliers of this product. *Id.* Respondent, however, had invoices only for 851,671 units. *Id.* Apparently, Respondent was also missing invoices for other products.[34] *Id.*

Respondent's CFO testified that upon being provided with a copy of the Government's audit, he proceeded to conduct his own audit. With respect to product # 17902, which the Government had concluded was short, the CFO testified that the DIs had "excluded a transaction for 28,800 units where we sent that product back to the original manufacturer" because in his words, it "was an obsolete item." Tr. 2036; RX 36, at 4. The ALJ further found credible the CFO's testimony that he had provided this information to the DIs as part of their document request. *Id.*; *see also* ALJ at 42.[35] Respondent also introduced into evidence numerous documents listing inventory adjustments and data pertaining to items that had been removed to the "obsolete inventory area" which its CFO asserted had been excluded by the DIs in doing the audit. Tr. 2037; RX 36. As for Respondent's other product (# 17903), which the

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[34] The DI also testified that there were thirty-four sales routes for which Respondent did not provide address information indicating where its products were being shipped to. Tr. 1197-98. GX 67.

[35] The ALJ noted that this document shows a return of 57,600. ALJ at 43. That figure appears, however, to be the amount of the credit Respondent was entitled to. RX 36, at 4.

Government concluded it was short nearly 33,000 units, Respondent introduced into evidence two documents listing various inventory adjustments which it contended had not been considered by the Government and which would have greatly reduced the discrepancy. GX 36, at 2. On cross-examination, the CFO maintained that he had provided these documents no later than July 18, 2007. Tr. 2085. Notably, the Government did not rebut either the CFO's testimony that the documents had been provided or that it had failed to consider them in performing the audit.

Respondent's CFO also testified that the additional audit (performed on the four products) was flawed, asserting that with respect to two of the items (#s 17121 and 17125), the Government had "exclude[d] a very large receipt that's on the sales record from those suppliers." Tr. 2038-39. With respect to product # 17121, the CFO testified that the Government had excluded "227,664 units [that] were listed on the report as sold to" it. *Id.* at 2039. As for product # 17125, which came from two suppliers, the CFO stated that the Government had excluded transactions totaling 160,000 units. *Id.*

While the purpose of the second audit was to obtain information from Respondent's suppliers and verify it with Respondent's reported receipts, in fact, the audit appeared to have been based on Respondent's actual invoices and not the reported figures

(which appear to have been used in the first round of audits). *Compare* GX 69, *with* GX 4, at 3.[36] In his testimony, however, Respondent's CFO did not address the Government's contention that Respondent was missing various invoices of its receipts and Respondent does not cite to any specific evidence of record rebutting the allegation. *See* Tr. 2042 (CFO testified that "I think in a couple of instances – I did not include the pages in this [exhibit RX 36], for example, Item 17121 when the Government excluded the 227,000 units."). Accordingly, I find that Respondent was missing numerous invoices documenting its purchases from its suppliers.

Respondent's Post-Suspension Conduct

Following the issuance of the suspension order, Respondent engaged in discussions with BDI, Inc., one of its suppliers, under which Respondent proposed to have its sales persons take orders for SLCs,

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[36] For example, both Respondent and the manufacturer agreed that Respondent had obtained 656,688 packets of product # 17121, but Respondent's invoices only added up to 429,024 units. GX 69. In the first audit, the Government used the 656,688 figure, and in the second audit, which was supposedly based on the information it obtained from the manufacturer, it used the 429,024 figure. *See* GX 4, at 3. It did the same thing with respect to product # 17125, using the 1,011,901 figure (which Respondent and the two manufacturers agreed with) in the first audit. *Id.* Again, in the second audit, it used the 851,671 figure, the figure that was based on the actual invoices produced by Respondent. *Id.*; *see also* GX 4, at 3.

which would then be sent back to its headquarters and forwarded on to BDI, which would fill the orders by shipping them to its customer by UPS. GX 48; Tr. 2401-02. According to a February 8, 2008 letter which was signed by its CEO, under the scheme, Respondent's sales persons would "still do all reordering and stocking of the merchandise as we have in the past," and when a shipment arrived at a customer, "the manager [would] have the choice of stocking the OTC cabinet or holding it for our sales person." GX 48. The letter further stated: "This basically keeps the business the same. The only difference is a UPS box. All invoices are from Novelty, Inc." *Id.*

Respondent's Vice President of Product justified the scheme, reasoning that under his "definition of sales, we're not involved in the distribution of the product. But our sales people are in that store functioning as an agent." Tr. 2402.

Because BDI refused to participate, the scheme "was never implemented." *Id.* at 2403. However, at the hearing, Respondent's VP testified that the scheme was "[s]omething that we're still continuing to explore." *Id.*

Discussion

Section 304(a) of the Controlled Substances Act provides that a registration to distribute a list I chemical "may be suspended or revoked * * * upon a finding that the registrant * * * has committed such acts as would render [its] registration under section

823 of this title inconsistent with the public interest as determined under such section," 21 U.S.C. 824(a)(4). Moreover, under section 303(h), "[t]he Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest." 21 U.S.C. 823(h). In making the public interest determination, Congress directed that the following factors be considered:

> (1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
>
> (2) Compliance by the applicant with applicable Federal, State, and local law;
>
> (3) Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
>
> (4) Any past experience of the applicant in the manufacture and distribution of chemicals; and
>
> (5) Such other factors as are relevant to and consistent with the public health and safety.

Id. 823(h).

"These factors are considered in the disjunctive." *Joy's Ideas,* 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in

determining whether a registration should be revoked or an application for a registration should be denied. *See, e.g., David M. Starr,* 71 FR 39367, 39368 (2006); *Energy Outlet,* 64 FR 14269 (1999). Moreover, I am "not required to make findings as to all of the factors," *Hoxie v. DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall v. DEA,* 412 F.3d 165, 173-74 (DC Cir. 2005).

In this matter, I have considered all of the statutory factors.[37] While I have found that several of the Government's allegations have not been proved, I nonetheless conclude that Respondent does not maintain effective controls against diversion and that its distribution practices and recordkeeping did not comply with Federal law. Moreover, while I have carefully considered the ALJ's findings regarding Respondent's willingness to comply with Federal law and her recommendation that I continue its registration with conditions, I conclude that on balance, the ALJ did not give sufficient weight to several factors including Respondent's failure to enforce its own policies, its sustained conduct in continuing to distribute out of unregistered storage facilities even after being advised that its practice was illegal, and its attempt to circumvent the suspension order. Accordingly, Respondent's registration will be revoked.

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[37] I note that there is no evidence that Respondent has been convicted of an offense related to controlled substances or listed chemicals.

Factor One – Maintenance of Effective Controls Against Diversion

Under agency decisions, this factor encompasses a variety of considerations. *Holloway Distributing, Inc.*, 72 FR 42118, 42123 (2007). These include the adequacy of the registrant's/applicant's security arrangements, the adequacy of its recordkeeping and reporting, its distribution practices, and the occurrence of diversion. *See id.*; *see also Rick's Picks, L.L.C.*, 72 FR 18275, 18278 (2007); *John J. Fotinopoulos*, 72 FR 24602, 24605 (2007); *D & S Sales*, 71 FR 37607, 37610 (2006); *Joy's Ideas*, 70 FR 33195, 33197-98 (2005).

In evaluating a registrant's security controls and procedures, DEA regulations direct that the Agency consider the following eight factors:

> (1) The type, form, and quantity of List I chemicals handled;
>
> (2) The location of the premises and the relationship such location bears on the security needs;
>
> (3) The type of building construction comprising the facility and the general characteristics of the building or buildings;
>
> (4) The availability of electronic detection and alarm systems;
>
> (5) The extent of unsupervised public access to the facility;

> (6) The adequacy of supervision over employees having access to List I chemicals;
>
> (7) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel in areas where List I chemicals are processed or stored;
>
> (8) The adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.

21 CFR 1309.71.[38]

It is undisputed that Respondent maintains adequate physical security of the list I chemicals which it stores at its registered location. The record further establishes, however, that Respondent then ships the SLCs to between 150 to 180 self-storage units throughout the country, where the products may be kept for up to several days at a time before the route sales persons retrieve them. Tr. 534 & 667-68.

As found above, Respondent disputes that this practice constitutes storage. *See* Tr. 666 (Executive

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[38] Under DEA regulations, "[a]ny registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate may submit materials and plans regarding the proposed security controls and procedures either to the Special Agent in Charge in the region in which the security controls and procedures will be used, or to the Chemical Operations Section Office of Diversion Control" at DEA Headquarters. 21 CFR 1309.71(c).

testifying that: "That's a nonsense question. Now you're coming back into the definition of what is storage. We're not storing the product in that location."); *id.* at 672 ("We are not storing or keeping or whatever words you want to try and use, product in these warehouses, against the law."). Likewise, in its brief, Respondent engages in the tortured argument that it does not store products in the self-storage units because "[t]he definition of 'store' focuses on future, not present use," and it uses the units only for what it terms is an "immediate" and not a "future use." Resp. Br. 99.

This argument begs the question of why Respondent needs to rent storage units if not to store products in them. Moreover, the record is clear that the products are typically not immediately transferred from the delivery truck to the route salesperson and that products may remain in the storage unit for up to several days before the route sales person retrieves them. Respondent is therefore using the self-storage areas for storage.

Moreover, putting aside momentarily the issue of whether these storage units must be registered, it is unlikely that they could meet the security requirements of this Agency. Indeed, DEA has previously rejected applications of entities that sought to store SLCs in public storage facilities on the ground that they present an unacceptable risk of diversion. *See Stephen J. Heldman,* 72 FR 4032, 4034 (2007); *see also Sujak Distributors,* 71 FR 50102, 50104 (2006).

In these decisions, I have noted a variety of security concerns which are raised by these facilities including the inadequacy of their construction, the lack of alarm systems, the lack of 24 hour on-site monitoring, the ability of unauthorized persons to gain access to the facility and the storage units, and the fact that the tenant does not control what other tenants the landlord rents to. *See, e.g., Sujak,* 71 FR at 50104. Here, for example, a former salesperson for Respondent testified that his storage unit was in a facility which lacked a secure perimeter and that anyone could come off the road and gain access to the door of his unit. Tr. 538. It also is undisputed that the storage units did not have separate cages within them for securing the products. *Id.* at 133. Finally, to this day, the Agency does not know where thirty-four of the storage units are located. Tr. 1196-98. Respondent's use of these storage facilities thus does not provide adequate controls against diversion and provides reason alone to support the finding that its continued registration "is inconsistent with the public interest." 21 U.S.C. 823(h).

The record identified a further serious deficiency in the security of Respondent's distribution practices. As found above, SLCs may remain on a salesperson's truck for up to nine days before being delivered to a store. This practice presents a serious security concern because of the risk that a thief can steal the vehicle's cargo. Indeed, by stealing the entire vehicle with its cargo – an act which takes but seconds to perform – a thief does not have to spend time

offloading the SLCs. *See McBride Marketing,* 71 FR 35710, 35711 (2006). Moreover, the risk posed by Respondent's distribution practice is exacerbated by the extensive time period during which the products remain on its trucks.

Nor are these security concerns the only manner in which Respondent fails to maintain effective controls against diversion. The record also supports the conclusion that Respondent has serious record-keeping deficiencies.

According to the manufacturer's sales journal, AAA Pharmaceuticals made three shipments of product # 17121 to Respondent: (1) 227,664 dosage units on August 11, 2006; (2) 228,264 dosage units on September 1, 2006; and (3) 200,760 dosage units on November 14, 2006. *See* GX 32 at 7, 8 & 11. Each of these shipments was also a "regulated transaction" as each exceeded the 1,000 gram threshold. 21 CFR 1310.04(f)(1)(ii). Respondent was thus required to keep a record of the transaction "for 2 years after the date of the transaction." *Id.* 1310.04(a). Yet Respondent was missing an invoice for the August 11, 2006 shipment of 227,666 units, GX 69, and the computer-generated records which it provided to the Agency pursuant to the warrant did not comply with Federal law and Agency regulations because they were missing required information such as the form of packaging and the method of transfer. *Compare* GX 34, *with* 21 U.S.C. 830(a)(2) and 21 CFR 1310.06(a).

With respect to product number 17103, Respondent acquired more than 525,000 units in seven different shipments between March 29, 2006, and April 19, 2006. *See* GX 3 at 2-5.[39] Here again, Respondent engaged in multiple regulated transactions and was required to keep records of them. *See* 21 U.S.C. 802(39); 21 U.S.C. 1310.04(f) (threshold for regulations transaction is based on "the cumulative amount for multiple transactions within a calendar month"). Yet it had no invoices for any of the shipments, GX 69, and the computer-generated records it provided to the Agency likewise did not comply with the regulations.[40] Respondent was also missing invoices documenting its purchases of other products. *See id.* Respondent's failure to maintain adequate records for the regulated transactions it engaged in constitutes not only a violation of Federal law, it also demonstrates that its systems for monitoring the receipt of SLCs are inadequate.

Respondent's systems for monitoring the distribution of its products are also deficient. First, Respondent's recordkeeping is deficient in various ways. According to the shipping records which Respondent

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[39] On March 29, 2006, AAA shipped Respondent 15,984 and 114,480 units of product number 17103; a dosage unit of this product contained 25 mg. of ephedrine hcl. GX 32 at 2-3. This was followed by a shipment on April 14, 2006 of 113,856 units; a shipment on April 17, 2006 of 113, 472 units; and three shipments on April 18, 2006 which totaled 167,328 units. *See id.*

[40] Here again, there were multiple transactions that fell within the definition of a regulated transaction.

provided to the DIs on July 9, 2007, it shipped more than 2300 packages of product # 17121 to three different salespersons on July 16, 2007, even though the date listed was a week into the future.

The Government also identified several instances in which Respondent's records indicated that it had distributed products that could not be lawfully sold under either the CMEA or the laws of Kentucky and North Carolina. While I have credited Respondent's evidence that the distributions did not occur, the evidence nonetheless points to further inadequacies in Respondent's recordkeeping and systems for monitoring the distribution of SLCs.[41] Moreover, Respondent's records contained a variety of errors related to the addresses of its customers including the wrong street address, and in one case, the wrong state.

Second, Respondent's procedures for monitoring the distribution of its products are deficient. The record establishes that the placement of an order and the delivery of the products occur simultaneously, and at the time, only the salesperson knows how much the store has purchased. Tr. 633. While Respondent asserted that it monitors its sales of SLC and conducts an inquiry if a store has acquired more inventory than is expected, and that another report is

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[41] I acknowledge the testimony of Respondent's executives that the errors were caused by its salespersons' erroneous entry of products codes into their computers, and that the software has since been reprogrammed.

prepared which lists instances in which more than one case has been sold per product during a transaction, these procedures are wholly deficient to protect against the diversion of SLCs. Moreover, as the evidence with respect to the 2002 incident in which Respondent's products were found at a meth. lab shows, under its distribution model, it can not identify which stores receive a particular product. Tr. 1517.

Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for legitimate purposes. *See* DEA, *Chemical Handler's Manual* 21 (2002).[42] Respondent's procedure of post-transaction review is incompatible with its obligation to identify and forgo suspicious transactions.

Respondent further maintains that its imposition of its one case, per product, per service cycle limit, and its practice of issuing warning letters to salespersons who sell over the limit, demonstrates that it maintains effective controls against diversion. However, the credited testimony establishes that between January and July 2007, Respondent's sales force

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[42] Under the Agency's policy, this manual was provided to all list I chemical distributors at various inspections. It is also available through the Agency's Web site.

violated its case limit policy some 85 times. ALJ at 12. Moreover, one of Respondent's senior executives testified that it had only started issuing written warnings in August 2007, which, of course, was after the administrative inspection. Furthermore, Respondent's policy is a meaningless measure because it sells ten different products and most stores are serviced every two weeks.

The inadequacy of Respondent's control measures is further demonstrated by its own exhibit showing its sales of SLCs in the three months prior to the issuance of the suspension order. As found above, Respondent's CEO testified that its average customer sold SLCs with a retail value of $640 per month. Tr. 563-64. Yet Respondent's evidence shows that during this period, it had sold SLCs with an average monthly retail value of more than $2000 (more than three times its average monthly sale) to approximately 120 of its customers, and SLCs with an average monthly retail value of more than $3000 (4.68 times its average monthly sales) to thirty-four of its customers. RX 27A. Moreover, Respondent sold SLCs with an average monthly retail sales value greater than $4000 to nine customers. *Id.* One of these customers was purchasing SLCs with an average monthly retail sales value of $5056 – approximately eight times its average customer's purchase. *Id.* Finally, its largest customer (Store # BPM55) was purchasing SLCs with an average monthly retail sale value of $7314 – more than eleven times its average customer's purchase –

in the three months prior to the issuance of the suspension order.

Moreover, the record establishes that Respondent had previously determined that store BPM55 was purchasing excessive quantities. RX 56. Yet notwithstanding this store's history, Respondent allowed it to purchase quantities that dwarfed that of its average customer. Furthermore, upon reviewing this store's logbook for the period July 21 through August 21, 2007, at least five individuals had purchased in excess of nine grams within this period. These customers purchased quantities which far exceeded the recommended dosing for the product's use as an asthma treatment[43] and are consistent with diversion.[44]

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[43] These five customers had purchased between 1,002 and 1,548 tablets. In contrast, Respondent's recommended dosing for its 12.5 mg product was "2 tablets every 4 hours as needed, not to exceed 12 tablets in 24 hours," and to "stop use" and see a doctor if "cough lasts more than 7 days." RX 9, at 3.

I acknowledge that Respondent cannot review the logbooks. A registrant cannot, however, ignore other evidence which is indicative of diversion.

[44] At the hearing, Respondent's Expert testified that BPM55 is an outlier and that it would not be appropriate to draw "a conclusion about [Respondent's] customers based on relying on the . . . highest seller." Tr. 1722. Contrary to the understanding of Respondent's Expert, in evaluating the effectiveness of an entity's diversion controls, there are no free passes. Excessive sales to a single store are sufficient by themselves to support the conclusion that the registrant does not maintain effective controls against diversion. Moreover, as

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Contrary to Respondent's understanding, while proof that a distributor is selling quantities in excess of the national monthly average for sales of SLCs by convenience stores would be highly probative of the distributor's lack of effective controls against diversion, it is not the sole measure for evaluating the effectiveness of those controls. More specifically, a registrant cannot ignore evidence that some of its customers are purchasing quantities that greatly exceed what its typical customer buys from it. Significantly, Respondent introduced this evidence into the record. Although in some instances there may be a plausible explanation for the disparity that does not involve diversion, Respondent offered no explanation that was specific to any store for why it was selling in such quantities.[45]

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explained above, BPM55 had a history of excessive sales and had previously come to the attention of Respondent. Yet Respondent continued to sell to it, and sold massive quantities to it in the three months which preceded the suspension.

For similar reasons, I find unpersuasive the testimony of Respondent's Expert that it would be error to draw conclusions from the six stores identified in Government Ex. 38 and 44. *See* Tr. 1697-1705. Indeed, with the exceptions of BPM 55 and NOC 56, it is not even clear that these stores were the largest purchasers.

[45] As noted above, there was a substantial dispute between the parties over the various assumptions necessary to determine what an average convenience store would sell in legitimate commerce. Yet even indulging numerous assumptions favorable to Respondent such as: (1) That only 31,000 stores sell the products, (2) that ephedrine products constitute sixty percent of the SLC market at convenience stores, and (3) that the NACS

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Moreover, while Respondent's CEO testified that he would cut off a customer who purchased more than a case of a product, Respondent offered no evidence that it has ever refused to sell to a customer because the customer was purchasing excessive amounts of products. Indeed, Respondent's continued sales to BPM55, at a rate that was more than eleven times what its average customer was buying, amply demonstrates that its purported written policy of monitoring those stores which purchased "unusual quantities," and "[i]f further unusual activity is noted * * * discontinu[ing] sales," RX 10, at 1; is a sham.

I therefore conclude that Respondent does not maintain effective controls against diversion. Given the variety of ways in which Respondent's controls are deficient, this factor strongly supports the

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survey has an error rate of fifty-five percent because some stores erroneously report their sales of ephedrine as general merchandise rather than as cold and cough products, ALJ Ex. 15; and concluding that the average monthly sales figure is $941 a month, more than 100 stores were selling at levels which were statistically significant according to Respondent's expert. *See* Tr. 1700 (noting that being outside of two standard deviations is statistically significant); *id.* at 1704 (use of two standard deviations is "a very appropriate number").

I acknowledge that because two standard deviations represents ninety-five percent of a population, by definition 2.5% of the stores will fall outside of this point on both sides of the curve. In concluding that Respondent does not maintain effective controls against diversion, I do not rely solely on the Z scores calculated by Respondent's expert. *See* RX 27A. I also consider the disparity between the size of the purchases of Respondent's largest customers and its average customer.

conclusion that Respondent's continued registration "is inconsistent with the public interest." 21 U.S.C. 823(h).

Factor Two – Respondent's Compliance With Applicable Laws

The Government further argues that Respondent failed to comply with Federal law and DEA regulations by distributing SLCs from the self-storage units because none of the units were registered. *See* Gov. Exceptions 1-6. The ALJ while noting that the facts surrounding Respondent's use of the self-storage units were not in dispute, declined to address the statutory issue, reasoning that because there was then litigation pending in the U.S. District Court, the Court, and not this proceeding, is the proper forum for resolving the dispute. ALJ at 91 n.38.[46] I conclude, however, that there is no reason for the Agency to not address this issue which involves a fundamental question as to the scope of the CSA's registration requirements.[47]

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[46] The ALJ did note, however, that Respondent ignored the letter of a DEA Group Supervisor which had informed it that its conduct was illegal. ALJ at 91.

[47] Ordinarily, courts defer to agencies when presented with a legal issue that lies within the agency's primary jurisdiction. II Richard J. Pierce, Jr., *Administrative Law Treatise* 917 (4th ed. 2002). The scope of the CSA's registration requirements is such an issue.

Under Federal law, "[e]very person who * * * distributes any * * * list I chemical * * * shall obtain annually a registration issued by the Attorney General." 21 U.S.C. 822(a)(1). "Persons registered by the Attorney General * * * to distribute * * * list I chemicals are authorized to possess [and] distribute * * * such * * * chemicals * * * to the extent authorized by their registration and in conformity with the other provisions of" the CSA. *Id.* § 822(b). The Act further provides that "[a] separate registration shall be required at each principal place of business * * * where the applicant * * * distributes list I chemicals." *Id.* § 822(e); *see also* 21 CFR 1309.23(a) ("A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported by a person.").

With respect to SLC distributors, DEA has created by regulation two limited exceptions to the requirement that each principal place of business be registered. The first is for "[a] warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered[.]" 21 CFR 1309.23(b)(1).[48] This

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[48] The regulation also exempts from registration "[a]n office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals (other than chemicals for display purposes) nor serves

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regulation is directly applicable to Respondent's use of the storage units.

Notably, at the time this regulation was promulgated, several commenters "objected to the requirement * * * that a separate registration be obtained for each location at which List I chemical activities are carried out[,]" and "suggested that DEA allow companies to obtain a single registration * * * for multiple locations." Implementation of the Domestic Chemical Diversion Control Act of 1993, 60 FR 32447, 32448 (1995). As DEA then explained, "[t]he law is specific on this point. The [Domestic Chemical Diversion Control Act] requires that *a separate registration be obtained at each location at which List I chemicals are distributed*." *Id.* (emphasis added).

Relatedly, several commenters asked "how the requirement for separate registrations for separate locations would apply to [independently owned] warehouses?" *Id.* DEA explained that "[t]he person who distributes List I chemicals from independently owned warehouses *must register at each location* and ensure that the other chemical control requirements, including security, record keeping, reporting, etc., for their products are met." *Id.* (emphasis added).

The record here clearly establishes that the SLCs which Respondent stores in the self-storage units are

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as a distribution point for filling such sales orders." 21 CFR 1309.23(b)(2). This provision is not applicable to Respondent's use of the self-storage units.

not shipped back to Respondent's registered location before being distributed. Rather, the SLCs are distributed directly from the self-storage units to Respondent's customers. As DEA's regulation makes plain, Respondent's self-storage units are therefore subject to the registration requirement. *See* 21 CFR 1309.23(b)(1).

As explained above, Respondent's contention that it was not storing products at the self-storage units is absurd. The units are warehouses as that term is understood in common usage. *See Webster's Third New International Dictionary* 2576 (1976) (defining warehouse as "a structure or room for the storage of merchandise or commodities").

Respondent nonetheless argues that the drop-off points are not required to be registered because they are not its "principal place of business." Resp. Br. at 97-98. Respondent acknowledges that the term "principal place of business [is] not defined in the definition section [] of the CSA." Resp. Br. at 97. Respondent thus contends that the term should be given its "ordinary meaning." *Id.* Relying on several cases interpreting the term "principal place of business" for the purpose of determining a corporation's citizenship for the diversity jurisdiction of the federal courts, *see* 28 U.S.C. 1332(c)(1), Respondent contends that "[t]he principal place of business for a corporation is usually its headquarters, where day-to-day business is conducted." *Id.* (citing *Heritage Educ. Trust v. Katz,* 287 F.Supp.2d 34 (D.D.C. 2003) and

Masterson-Cook v. Criss Bros. Iron Works, Inc., 722 F. Supp. 810, 812 (D.D.C. 1989)).

According to Respondent, the Federal courts apply a "'nerve center of operation' test to establish the principal place of business of corporations doing business in multiple states[,]" and that "[w]hen no one state is clearly the center of corporate activity or accounts for a majority of the company income, the headquarters logically assumes greater importance in determination of the principal place of business." *Id.* at 97-98 (quoting *Masterson-Cook,* 722 F. Supp. 812) (other citations omitted). In Respondent's view, its Greenfield, Indiana headquarters "is clearly the center of corporate activity," because "[a]ll transactions with vendors and customers are handled through the Greenfield offices." *Id.* at 98. Relatedly, Respondent argues that "[t]he drop off units are not the 'center of corporate activity' nor do they 'account for a majority of the company income.'" *Id.* Respondent's arguments are not persuasive.

It is fundamental that statutory terms take their meaning from the context in which they are used and the statutory purpose. *See Mid-Con Freight Systems, Inc., v. Michigan Pub. Serv. Comm'n,* 545 U.S. 440, 447 (2005); *Tyler v. Cain,* 533 U.S. 656, 662 (2001); *see also Pharmaceutical Res. & Mfr's of America v. Thompson,* 251 F.3d 219, 224 (D.C. Cir. 2001). Respondent's reliance on cases interpreting the diversity statute ignores the context in which the term "each principal place of business" is used in the CSA, as well as the CSA's fundamentally different purpose.

Under Respondent's interpretation, an entity would be required to obtain a registration only for a single location – its headquarters. The text of section 822 demonstrates, however, that Congress did not limit a registrant's obligation to obtain a registration to a single place of business such as its corporate headquarters. Rather, Congress imposed on a registrant the obligation to obtain a separate registration at "*each* principal place of business * * * where the applicant * * * distributes * * * List I chemicals." 21 U.S.C. 822(e) (emphasis added).

Consistent with the underlying purposes of the CSA, the statutory text manifests Congress's understanding that an entity can have multiple principal places of business. A location where List I chemicals are stored and distributed from, is a principal place of business because it plays a "consequential" part in the registrant's activity of distributing. *See Webster's Third New Intl Dictionary* 1802 (1976) (defining "principal" in part as "consequential"). In determining whether a facility is a principal place of business within the meaning of the CSA, the Act looks to the nature of the activity that occurs at the particular location and not at the dollar volume of business that is transacted out of the facility. *See* 21 CFR 1309.23(b)(2) (exempting from registration "[a]n office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals * * * nor serves as a distribution point for filling sales orders").

Respondent's interpretation would clearly frustrate the Congressional purpose. In enacting the CSA's registration provisions, Congress' purpose was to protect against diversion by requiring that those persons who propose to engage in the legitimate distribution of controlled substances and listed chemicals apply for a registration, notify this Agency of the proposed location of their activity, and submit the facility for inspection by the Agency to ensure that it has adequate security controls and procedures. *See, e.g.,* 21 U.S.C. 822(f) (authorizing the Attorney General "to inspect the establishment of a registrant or applicant for registration"). Indeed, inspection by the Agency of a proposed facility is fundamental to the CSA's mandate to protect the public interest. *Id.* 823(h); *see also* 21 CFR 1309.41.

As the record here establishes, Respondent has never applied for registration for any of its storage units and has never submitted any of its storage units for inspection. Indeed, according to the record, Respondent has yet to provide information regarding the location of some 34 of its storage units. As this case demonstrates, adopting Respondent's interpretation would frustrate Congress's purpose and render the Act a nullity.

Respondent's interpretation would also create a perverse incentive. While it is unclear whether under its view an entity which has only a few warehouses would have to obtain a registration for each of them,

see Resp. Br. at 97-98,[49] what is clear is that an interpretation which determines whether a facility must be registered by looking to the amount of business activity that occurs out of a facility rather than the nature of the activity that occurs therein, would encourage an entity to keep adding warehouses or storage facilities so that it could eventually claim that its warehouses were no longer principal places of business and were thus not subject to the registration requirement. Adopting Respondent's interpretation would thus lead to absurd results and seriously undermine the security of the Nation's controlled substances and listed chemical supplies. I therefore reject it.

As stated above, the ALJ did not address this statutory question. She did, however, conclude that Respondent's conduct in continuing to store SLCs at, and distributing them from, the self-storage units, even after receiving the Group Supervisor's letter, was "not consistent with the requirements for a participant in a regulated industry," and supported the revocation of its registration. ALJ at 91. Respondent excepts to the ALJ's conclusion, contending that it was placed in the "dilemma" that if it complied with the letter, it would have to use

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[49] Respondent's argument that "the principal place of business for a corporation is usually its headquarters," Resp. Br. 98, suggests that its view is that only one registration is required for an entity no matter the geographic scope of its distribution activities.

common carriers and that this "would increase the risk of diversion." Resp. Exceptions at 99. Respondent further argues that because it "questioned the legal validity of the letter, and feared adherence to it would cause [it] to contribute to the risk of diversion to the illicit methamphetamine trade, it filed suit" in federal court. *Id.* at 100.

Respondent's argument is patently self-serving and unsupported by the record. As found above, Respondent's evidence as to the perceived security inadequacies of, and increased risk of diversion when shipping via common carriers, lacked foundation. It presented no evidence of any diversion of SLCs when being shipped by common carriers.[50] The argument further ignores the significant risk of diversion posed by its own distribution model, both through its use of the storage units which do not provide an acceptable level of security, and its further practice under which SLCs may be stored on a salesperson's truck for up to nine days at a time.

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[50] Respondent also argues that "the Raber letter would allow reliance on a system of distribution (FedEx and UPS unregistered locations) that present risks of diversion that exceed those of [its] system." Resp. Exceptions at 101. Congress however, has specifically exempted common carriers from registration, *see* 21 U.S.C. 822(c)(2), and has concluded that their use for shipping controlled substances and listed chemicals poses an acceptable risk of diversion. I further note that Respondent acknowledged in testimony that it has used common carriers in the past.

Finally, Respondent contends that because it was not sure what the legal effect of the letter was, it felt obliged to challenge the letter by filing suit. Contrary to Respondent's view, its right to seek declaratory relief in federal court is not at issue. *Cf. id.* at 100. (arguing that ALJ's decision "[c]ondemns the exercise of" its right to seek relief in a federal court). Rather, what is at issue is Respondent's decision to continue to distribute SLCs – for some forty-four months – in a manner that violates Federal law, and its doing so even after being told that it was violating Federal law.

Furthermore, even if there was a legitimate question as to the legal effect of the letter, the Agency's regulation made clear that a warehouse was not exempt from registration if the SLCs being stored therein "are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered." 21 CFR 1309.23(a)(1). I thus conclude that the Agency's regulation and the letter provided Respondent with ample notice that its conduct was illegal.[51] Notwithstanding Respondent's assertion that it is now willing to comply with Federal law, its deliberate disregard of

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[51] Nor did Respondent seek review of the Group Supervisor's letter within the Agency.

the warning it received and lengthy failure to comply, strongly support the revocation of its registration.[52]

Factor Four – Past Experience in the Distribution of Chemicals

In discussing this factor, the ALJ noted that Respondent has been registered since 1998 and thus had extensive experience in distributing SLCs. ALJ at 92-93. She further explained that prior to the service of the Suspension Order, "Respondent had not been informed by the [agency] of any incidents of diversion of its SLC product," and that with the exception of the 2004 letter regarding its distribution practices, it was "never informed * * * of any statutory or regulatory violations." *Id.* at 93. Finally, the ALJ noted that the Agency had renewed "Respondent's registration annually between 1998 and 2007." *Id.* Based on what she characterized as Respondent's "nine year history of compliance," the ALJ concluded that the evidence on this factor "support[ed] a remedy less severe than revocation." *Id.*

The ALJ's conclusion is mistaken for several reasons. First, the ALJ's conclusion that Respondent had not been informed by the Agency of any incident of diversion is contrary to the evidence, which establishes that twenty-two sixty-count bottles of products

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[52] As noted under factor one, Respondent also failed to comply with Federal law because it did not maintain proper records of regulated transactions.

it distributed were found at an illicit laboratory in Connecticut and that a DI discussed the matter with its executives. Tr. 1082-84. Whether the subject was first broached by the DI or Respondent is beside the point, as is whether the information was put in a formal warning letter. The fact remains that products which it distributed were diverted. Moreover, while Respondent provided the investigator with information as to which of its salespersons had received the products, it could not identify the stores to which the products were distributed. Tr. 1517.

Second, the ALJ gave insufficient weight to Respondent's continuation of its illegal practice of distributing out of unregistered storage units for more than three and a half years after having been advised of the practice's illegality. Most significantly, at no point did Respondent voluntarily cease the practice.

Moreover, as explained above under factor two, the registration requirement is one of the essential features of the CSA. Respondent's violations are not technical violations of the Act. Respondent's conduct thus precludes a finding that Respondent's experience establishes a "history of compliance." ALJ at 93. Respondent's experience thus also supports the conclusion that its registration would be "inconsistent with the public interest." 21 U.S.C. 823(h).[53]

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[53] The ALJ's further reliance on the Agency's renewal of Respondent's registration was in error. Under Federal Regulations, in the event the Agency proposes the denial of a renewal

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Factor Five – Other Factors Relevant to and Consistent With Public Health and Safety

As found above, following the service of the Immediate Suspension, Respondent contacted one of its suppliers and attempted to enter into a scheme under which its sales force would continue to take orders for SLCs, which would be sent to its headquarters and then on to the supplier, which would ship the products. Under the scheme, Respondent's salespersons would "still do all reordering and stocking of the merchandise as [they] have in the past." GX 48.

At the hearing, one of Respondent's vice presidents attempted to justify the scheme, explaining that under his "definition of sales, we're not involved in the distribution of the product. But our sales people are in that store functioning as an agent." Tr. 2402. While the supplier refused to enter into the scheme, the VP testified that it was "[s]omething that were [sic] still continuing to explore." *Id.* at 2403.

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application, it must issue an Order to Show Cause, 21 CFR 1309.42(a). There are a variety of reasons why the Agency may not be prepared to go forward with a Show Cause Proceeding at a particular time including, *inter alia*, a lack of resources, the complexity of the matters under investigation, and the need to pursue other enforcement priorities. Moreover, field personnel may approve the renewal of a registration based on an erroneous understanding of the law and regulations. The decision to renew a registration is thus not probative of a registrant's record of compliance with Federal law and Agency regulations.

In its Exceptions, Respondent contends that "[u]nder 21 CFR 1309.23, sales agents are not required to be registered and are lawful." Resp. Exceptions at 102. Respondent further argues that because it "only discerned select customer's interest in it serving in this role," *id.* at 103, the ALJ's conclusion that it "still does not seem to understand that it is working in a highly regulated industry when it actually handles SLC products," ALJ at 92, condemns it based on "the mere expression of interest in a legal option." Resp. Exceptions at 103.

Respondent is correct that because it never actually entered the scheme, there is no basis for concluding that its actions related to the scheme demonstrate that it failed to comply with applicable laws. *See* 21 U.S.C. 823(h)(2). The scope of factor five is, however, considerably broader than factor two, and encompasses "such other factors as are relevant to and consistent with the public health and safety." *Id.* 823(h)(5).

Respondent's assertion that it merely expressed interest in a legal option mischaracterizes the record. Respondent's actions were not limited to merely thinking about a legal option or seeking legal advice about the scheme. Rather, it affirmatively sought out one of its suppliers and attempted to induce it to enter the scheme only to be rebuffed by the supplier.

While Respondent maintains that it was pursuing a legal option because an agent is not required to be registered, it ignores that this exception applies

only if the "agent * * * is acting in the usual course of [its] business." 21 U.S.C. 822(c)(1); 21 CFR 1309.24(a). The usual course of Respondent's business with respect to SLCs did not, however, involve acting as a sales agent for another registrant. Rather, the usual course of its business was distributing SLCs for its own account. More significantly, I further hold that an entity does not act in the usual course of business when it engages in distribution-related activities that it has previously been prohibited from doing pursuant to an order suspending or revoking its registration. It would fundamentally undermine the CSA's purpose of protecting against diversion to allow an entity whose registration has been suspended or revoked to subsequently engage in the same or related activities as an agent.

Respondent's attempt to circumvent the suspension order – and the admission of one [sic] its executives at the hearing that it was still exploring this option – reflects adversely on its fitness to engage in the distribution of SLCs. I thus conclude that this factor also supports the conclusion that Respondent's registration would be "inconsistent with the public interest." 21 U.S.C. 823(h)(5).[54]

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[54] As explained above at n. 5, the issue of whether there is a legitimate medical need for over-the-counter ephedrine products, *see* ALJ at 94-95, is for the FDA to decide. The issue in this proceeding is whether Respondent's registration is consistent with the public interest.

Sanction

Under DEA precedent, the Agency considers all of the facts and circumstances in determining the appropriate sanction. *See Martha Hernandez, M.D.*, 62 FR 61,145 (1997). While the ALJ found that factors one and two supported revocation, and that "Respondent's actions appeared to blatantly disobey a DEA directive," she further reasoned that except for this letter, "Respondent has not been given an opportunity to remedy the flaws identified * * * in this action." ALJ at 100. Based on what she characterized as its "history of compliance, as evidenced by" the Agency's continuing its registration, as well as "its financial commitment to compliance, as evidenced by its rework of its hand-held computer system to better track inventory," the ALJ reasoned that revocation "does not seem consistent with prior agency action concerning this Respondent." ALJ at 100-101. Based on this view of the record, the ALJ further opined "that this is a case where teamwork between the DEA and this major distributor would facilitate the public interest." *Id.* at 101. The ALJ thus recommended that I continue Respondent's registration while imposing compliance conditions.

Were the evidence limited to Respondent's recordkeeping problems, imposing compliance conditions might well protect the public interest. But it is not. I acknowledge that the evidence points to some measures which Respondent voluntarily undertook such

as reprogramming its computer system,[55] providing its customers with materials on the CMEA and its self-certification requirement, logbooks, and plexiglass cabinets. Its customers could not, however, legally sell its products without self-certifying and maintaining logbooks. Moreover, these measures do not address the serious problems with its distribution practices that are established by the record, and which were either ignored, or discounted by the ALJ.

First, for more than three and a half years, Respondent disregarded a DEA letter specifically warning it that its use of the 150-180 self-storage units to store and distribute SLCs violated Federal law. Moreover, Respondent continued to violate Federal law up until its registration was suspended. As explained above, these are not technical violations, but rather transgressions of one of the CSA's fundamental provisions. Respondent's disregard of the letter and continuation of its practices for some forty-four months makes its conduct especially egregious. Given the sustained nature of the violations and Respondent's failure to voluntarily cease its misconduct, its assertion that it is now willing to "modify[ ] its existing system of distribution," Resp. Exc. 90, is not persuasive. *Cf. ALBA Laboratories, Inc., v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995) ("[a]n agency rationally may conclude that past performance is the

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[55] It is, however, unclear whether the reprogramming has rectified the problems identified with the salespersons' entry of product codes.

best predictor of future performance"); *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36503 (2007) (rejecting company's claims of reform in light of the scope and duration of its misconduct and failure to heed information that its activities were contributing to diversion).

Second, while Respondent asserted that it imposed sales limits on how much of each product a store could buy in a service cycle, and that it monitored the purchases of each product at each store throughout the week to determine whether a store was purchasing excessive quantities, investigated if it was, and cutoff sales to those store [sic] which were purchasing excessive amounts, it is clear that these policies were frequently ignored. Putting aside the effectiveness of the one case per product, per service cycle policy,[56] the credited testimony establishes that its sales force violated the policy some 85 times in the six months preceding the July 2007 inspection. Moreover, Respondent only started issuing warning letters to its sales force in August 2007 – a month after the warrant was executed – with one of its executives offering the lame excuse that he had not received the reports until then because of a computer "glitch."

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[56] As explained above, the policy's limit was imposed on a per-product and per-service cycle basis. Most stores were serviced every two weeks and some were serviced weekly. Moreover, Respondent sold ten different products. Accordingly, a store being serviced weekly could buy up to forty cases every four weeks.

Notably, Respondent's CEO testified that if a customer obtained more than a case of a product in a service cycle, he "would cut them off, [and] stop the sale of product to them." Tr. 159. Respondent, however, produced no evidence that it had ever entirely cut off a customer.

Indeed, Respondent's own evidence with respect to store BPM55 – a store at which five persons purchased quantities that are grossly inconsistent with use of the products to treat asthma and are consistent with diversion – amply demonstrates the disingenuousness of its claim that it monitors its customers' purchases and cuts off sales if a store is acquiring excessive amounts. Notwithstanding that it had previously developed concerns regarding this store's excessive purchases, in the three months prior to the suspension order, Respondent sold to it products with a monthly average retail value of more than $7300, an amount more than eleven times its average customer's purchase.[57] Respondent's sales to this store amply demonstrate that its policy of monitoring "unusual sales activity" and cutting off sales if such purchases continue, RX 10, at 1, is a sham and not a legitimate effort to control diversion.

Respondent's failure to enforce its own policies provides reason alone to conclude that it cannot be

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[57] As found above, the record also shows numerous other stores to which Respondent repeatedly sold quantities that exceeded its average customer's purchases by a wide margin.

trusted to adhere to compliance conditions. This conclusion is further supported by Respondent's sustained and flagrant violations of Federal law, as well as its attempt to circumvent the suspension order. Indeed, as Respondent's history amply demonstrates, its professed commitment to "teamwork" and to become a compliance model for the entire industry," Resp. Ex. at 139, cannot be taken seriously.[58] I therefore conclude that imposing compliance conditions would not adequately protect the public interest, and reject the ALJ's recommendation.[59]

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[58] For the same reasons, I find unpersuasive the August 13, 2008 letter from Respondent's President.

[59] Respondent raises a plethora of claims that the Agency or its personnel have violated its rights under the First and Fifth Amendments, as well as statutory provisions including the Administrative Procedure Act, the Data Quality Act, and 21 U.S.C. 880. *See* Resp. Br. at 114-39. For example, Respondent asserts that the DIs violated its First Amendment rights and engaged in a prior restraint because they refused to allow its executives to videotape them as they reviewed Respondent's records. *See id.* at 116. It also alleges that a DI committed an assault and battery during the inspection when he grabbed a video recorder from the hands of one of its executives who was attempting to set up the camera in order to tape the investigators while they reviewed Respondent's records.

While in my order denying Respondent's interlocutory appeal, I adhered to settled Agency precedent that the exclusionary rule does not apply in these proceedings, ALJ Ex. 13, at 3; Respondent now contends that I should discount the testimony of two DIs who participated in the inspection to deter future violations. Indeed, Respondent even contends that I should discount the testimony of these DIs based on the alleged assault and battery of the third DI, who did not testify at the hearing.

(Continued on following page)

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, 003563NSY, issued to Novelty Distributors, D/B/A/ Greenfield Labs, be, and it hereby is, revoked. I further order that any pending application of Novelty Distributors, D/B/A Greenfield Labs, for renewal of its registration, be, and it hereby is, denied. This order is effective immediately.

Dated: September 3, 2008.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. E8-21035 Filed 9-9-08; 8:45 am]

BILLING CODE 4410-09-P

Having considered the legal and factual bases for each of Respondent's claims, I conclude that none of them presents a substantial question as to the fundamental fairness of this proceeding and none warrants further discussion.

UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In the Matter of	Docket No. 08-33
NOVELTY DISTRIBUTORS	

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Gail A. Randall, Administrative Law Judge

Date: May 21, 2008

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I. PROCEDURAL BACKGROUND

On or about January 17, 2008, the Deputy Administrator, Drug Enforcement Administration ("DEA"), issued an Order to Show Cause and Immediate Suspension of Registration ("Order") to Novelty Distributors, d/b/a/ Greenfield Labs ("Respondent"), immediately suspending Respondent's DEA Certificate of Registration, 003563NSY, pursuant to 21 U.S.C. § 824(d), and seeking to revoke its DEA Certificate of Registration as a distributor of list I chemicals, pursuant to 21 U.S.C. § 824(a)(4), and to deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(h). The Government asserted that the basis for seeking revocation was that the Respondent's continued registration would be inconsistent with the public interest as defined by 21 U.S.C. §§ 823(h) and 824(a)(4). [Administrative Law Judge Exhibit (ALJ Exh.) 1].

The Respondent filed a timely request for an expedited hearing on February 26, 2008. ALJ Exh. 2]. The hearing was held in Arlington, Virginia, on March 24, 2008, through April 1, 2008. [ALJ Exh. 4; Transcript ("Tr.") volumes I through VIII]. At the hearing, both Counsel for the DEA ("the Government" or "DEA") and Counsel for the Respondent called

witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted Proposed Findings of Fact, Conclusions of Law and Argument.

On March 19, 2008, I issued a Protective Order in this case. [ALJ Exh. 9].

II. ISSUE

The issue in this proceeding is whether or not the record as a whole establishes by a preponderance of the evidence that the Drug Enforcement Administration should revoke the DEA Certificate of Registration, Number 003563NSY, of Novelty Distributors d/b/a Greenfield Labs, as a distributor of List I chemicals, pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications to renew or modify this registration pursuant to 21 U.S.C. § 823(h), because to continue the registration of Novelty Distributors would be inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(h) and 824(a)(4). [Tr. 5-6; ALJ Exh. 6].

III. FINDINGS OF FACT[1]

I find, by a preponderance of the evidence, the following facts:

A. *Respondent's Background Information*

1. Corporate Officers

1. The Respondent, is a wholesale distributor of novelties and scheduled listed chemical products ("SLC"). It was founded in 1984 by Mr. Todd Green ("Mr. Green"), who remains as the President and single shareholder of Novelty, Inc. [Transcript ("Tr.") 63-64].

2. The business' location and registered DEA address is 351 West Muskegon Drive, Greenfield, Indiana. [Tr. 65, 2269-73; Government Exhibit ("Govt. Exh.") 1; Respondent Exhibit ("Resp. Exh.") 11[2]]. The Respondent has been registered with the DEA since August of 1998, and the Greenfield location is its only registered location. [Tr. 65, 546-47; Govt. Exh. 1 at 2].

3. Mr. Merlau is the Respondent's Vice President of Product. [Tr. 542]. He is in charge of the

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[1] Given the magnitude of the transcript of these proceedings, both the electronic and hard copy versions of the transcript were used to prepare the findings of fact. I note to the parties that certain portions of the electronic and hard copy page numbers differ and regret any inconvenience this may cause the parties.

[2] Respondent's Exhibit 11 provides a schematic of the Respondent's working areas.

product development team, which designs products, develops art concepts, and submits product license requests. [Tr. 543]. He is also involved in the sampling, manufacturing, distributing, coordinating, and the timing of product handling. [Tr. 543]. Last year, the Respondent manufactured and introduced into its product line approximately 1,100 different products with individual stock-keeping unit ("sku") identifiers. [TR. 556]. None of these were SLC products, however. [Tr. 556].

4. At the hearing, Mr. Bledsoe credibly testified that the Respondent sells "more dollars in novelty items than we do in any other category." [Tr. 1398].

5. Mr. Ryan Polk is the Chief Financial Officer for the Respondent. [Tr. 1509] He actually handles the DEA registration paperwork. [Tr. 546]. He is also responsible for the accounting and financial reporting for the Respondent. [Tr. 1510]. Regarding compliance with the Controlled Substances Act, Mr. Polk would be responsible for the inventory accounting. [Tr. 111].

6. Mr. Mark Bledsoe has been the Director of Category Management since 2004, and he is responsible for determining what SLC products the Respondent carries. [Tr. 547, 553, 1274-76]. Mr. Bledsoe has been with the Respondent for approximately 10 years. [Tr. 1273]. Mr. Bledsoe has extensive experience in operations within the convenience store industry. [Tr. 1365-66].

2. Sales Representatives

7. The Respondent's sales representatives visit its convenience store customers every other week (90% of the customers are on this schedule), once a month (5% are on this schedule), and once a week (approximately 5% are on this schedule). [Tr. 1290]. The sales representatives are supervised by district managers, who are supervised by zone managers. [Tr. 2046]. Each district manager typically has five sales representatives to supervise, with a total of approximately 30 district managers. [Tr. 2047]. The Respondent also has 6 zone managers, who report to three regional vice presidents, who report to the Executive Vice President of Sales, who reports directly to the President, Mr. Green. [Tr. 2047-48].

8. The sales representatives are trained by both on-the-job training with experienced sales representatives, and also through the use of a training manual. [Tr. 2049, 2052-53; Resp. Exh. 28].

9. The training manual also teaches the sales representatives how to use the hand-held computer, which is used for inventory control in the field. [Tr. 2057-59; Resp. Exh. 28 at 64-67]. The sales representatives use this computer "to generate invoices, write credit tickets, see their schedule, (and) order product from their source warehouse." [Tr. 2060]. Personnel at the Respondent's headquarters reconcile the sales representatives' sales with service, shipment, and inventory records. [Tr. 2060-61]. The sales representatives are required to transmit all of the day's

transactions to the headquarters each night. [Tr. 2060; Resp. Exh. 28 at 93-95].

10. The Executive Vice President of Sales receives a weekly report showing "total inventory (of SLC products) for every route by week . . . " [Tr. 2061-62]. That is the first point of review of sales representatives' actions made by the operations managers. [Tr. 2061]. These reports also "compare sales and shipments to try and identify any instances where we think somebody is increasing their inventory more than what we would expect them to." [Tr. 2061]. If a sales representative is selling more than expected, the sales representative will be asked about the specific items on the weekly report, and a district manager or a zone manager will visit the sales representative to determine the actual inventory in question. [Tr. 2061-62].

11. Mr. Polk credibly testified that the sales representatives are monitored as follows:

> We monitor a lot of things with the route service professionals. We monitor service. We monitor sales. We monitor asset management between vehicle maintenance, truck maintenance. There are several reports generated every day to monitor the activities of the sales representatives.

[Tr. 2048]. For example, through this reporting process, Mr. Polk found that, when an inventory question arises, it is typically resolved by finding that the sales

representative made a mistake in ordering and received more product than was actually needed.

[Tr. 2061-62].

3. Respondent's Operations

12. The Respondent's only retail customers are convenience stores [Tr. 80-81]. It has had between 10,000 and 12,000 convenience store customers located in approximately 45 states. [Tr. 81, 127-28, 135-36, 1296]. Approximately 94-98% of its market are national, large convenience store chains with multiple unit operators, and approximately 6% are individual convenience stores. [Tr. 88-89, 114, 145-46, 1340, 2229-30].

13. For example, the Respondent has had major retail convenience store chain customers, to include convenience stores associated with the Exxon-Mobil Corporation (prior to 2006), Circle K, and The Pantry chains. [Tr. 111, 2265]. These companies have full-time staff, to include legal counsel, to ensure compliance with state and federal regulations. [Tr. 147].

14. Further, Mr. Green described these companies as "billion dollar companies which mostly are publicly traded." [Tr. 111]. Many of the Respondent's customers have gross receipts in excess of business entities such as major drug stores such as Rite-Aid, big box stores such as K-Mart, and grocery stores such as Food Lion. [Tr. 146]. The convenience stores sell products at retail directly to the end user. [Tr.143].

None of the Respondent's customers are distributors, but, rather, they are classified by the Respondent as customers who receive direct store delivery from the Respondent. [Tr. 143]. The Respondent does not sell SLC products in the wholesale market to other distributors. [Tr. 685-686].

15. Mr. Green classifies his product line as a "full service" line for convenience stores, to include over-the-counter products such as dietary supplements and SLC products, as well as sunglasses, lighters, and "impulse items." [Tr. 84, 87-88]. However, the SLC products are the only pharmaceutical products the Respondent carries in its inventory. [Tr. 552]. The Respondent carries combination ephedrine products and combination pseudoephedrine products as its only SLC products. [Tr. 79-80, 1277-78].

16. The Respondent sells SLC products to approximately 3,500 to 4,000 customers in approximately 30 different States. [Tr. 80-82, 558-60, 564]. These products are packaged in various quantities, to include a two, a six, a twelve, and a twenty-four count product. [Tr. 561]. The twenty-four count package is the largest count package the Respondent currently handles. [Tr. 692-93]. The six count product is the most popular selling SLC product, and the twenty-four count product generates the greatest amount of SLC-product revenue for the Respondent. [Tr. 561, *but see* 1297]. The ephedrine products are in a 12.5 mg strength and a 25 mg strength. [Tr. 616].

17. The brands of SLC product the Respondent carries are Double Action, Mini, and Ephedrine Plus. [Tr. 137; Resp. Exh. 9]. The Respondent also sold ephedrine under the Stackers label prior to the immediate suspension. [Tr. 137].

18. The Respondent's Double Action 24-count, 12.5 milligram ephedrine product has a suggested retail price of $10.99. [Tr. 562]. The Respondent sells an approximate average of $640.00 in SLC products to its convenience store customers per month, with the majority of the sales being of ephedrine-containing products. [Tr. 563-64]. For example, the record shows that, between November of 2007 and January of 2008, the Respondent distributed more than $640.00 retail value of SLC products on a monthly basis to 1,065 of its convenience store customers out of the 3,629 customers purchasing SLC products during that time frame. [Resp. Exh. 27A].

19. The ephedrine products are popular with the convenience store customers, and they have high profit margins. [Tr. 94]. The Respondent only sells orally ingested gel cap and tablet forms of ephedrine products. [Tr. 97]. The ephedrine products outsell all of the Respondent's other over-the-counter pharmaceutical products. [Tr. 98-99].

B. *Respondent's Handling of SLC Products*

1. Generally

20. Mr. Bledsoe is responsible for knowing the requirements of the Controlled Substances Act ("CSA") and the implementing regulations, and the relevant Federal Register-announced rules and regulations. He also maintains contact with other industry colleagues aware of SLC products' regulations. [Tr. 1328-29]. Mr. Bledsoe also monitors federal and state laws, and is charged with educating the Respondent's customers about the regulations that pertain to them. [Tr. 1288, 1326].

21. Mr. Merlau also acts as the compliance officer for the handling of SLC products, and he also coordinates Respondent's litigation. [Tr. 544]. Mr. Merlau and Mr. Polk are required to keep current regarding the regulations pertaining to the handling of the SLC products and to ensure all employees involved in the handling of these products are properly trained to act in compliance with the regulations. [Tr. 544-46].

22. Mr. Green, however, remains ultimately responsible for the Respondent's compliance with the Controlled Substances Act and the DEA's implementing regulations. [Tr. 545].

23. Mr. Bledsoe credibly testified that he does not hesitate to contact the DEA when he has compliance questions, especially after the enactment of

the Combat Methamphetamine Act ("CMEA"). [Tr. 1370-75; Resp. Exh. 15].

24. In 2004, the Respondent sold SLC products to approximately 8,000 customers. [Tr. 2362-63]. Just prior to the serving of the immediate suspension by the DEA, the Respondent sold SLC products to approximately 3,600 customers. [Tr. 2363]. Mr. Merlau credibly testified that the Respondent sold 3.7 million SLC products in the 52 weeks prior to the immediate suspension of its DEA registration. [Tr. 657, 675].

25. Since the enactment of the CMEA, the Respondent does not sell SLC products to customers who are not self-certified, as required by the Act.[3] [Tr. 554, 1354-62; Resp. Exhs. 16, 57 and 57A]. The Respondent does not sell products to convenience stores using its website, and at no time could a customer buy SLC products on its website. [Tr. 88, 93-95].

26. The Respondent carries a combination ephedrine guaifenesin product and a combination pseudoephedrine guaifenesin product. [Tr. 1278]. Specifically, the Respondent carries a 6-count, a 12-count, and a 24-count package of combination ephedrine product, in both a 12.5 mg strength and a 25 mg strength tablet. Further, the Respondent sells combination ephedrine products in the 12.5 mg and 25 mg strength gel capsules in the 6-count and the 24-count

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[3] The record does contain evidence that the Respondent's records do not accurately reflect this information. See section on recordkeeping, infra.

package. As for combination pseudoephedrine product, the Respondent carries a 2-count, 6-count, 12-count, and a 24-count package of 30 mg pseudoephedrine product. [Tr. 1397-99, 2276-78; Resp. Exh. 9]. "Double Action" is the brand name of a combination ephedrine product that is the Respondent's own exclusive brand product. [Tr. 1404].

27. The Respondent is the sole supplier of SLC products to its customers. [Tr. 626-27]. The Respondent knew that ephedrine products could be used to manufacture methamphetamine. [Tr. 1293].

28. The Respondent has a procedural briefing that highlights the procedures used in the storage area of the SLC products. [Govt. Exh. 13]. The Respondent has a written policy handbook for the handling of SLC products. [Tr. 1305; Resp. Exh. 10]. The Respondent also has a sales representative's training manual, which is used extensively to train its employees. [Tr. 1314, 2291-2294; Resp. Exh. 28]. The training manual describes various incentives and awards made to the sales representatives. [Tr. 1314-15; Resp. Exh. 28 at 6]. The Respondent also pays its sales representatives a base pay, a commission, and bonuses. As of the date of the Immediate Suspension, the commission for the sales of Double Action SLC product was 5%. [Tr. 1315-17; Resp. Exh. 28 at 4]. The Respondent gives the higher 5% commission on the Double Action brand because it is the Respondent's own private label brand; the Respondent wants to encourage the sale of this product over other company's SLC products, and the profit margins are

greater than on other brands of SLC product the Respondent distributes. [Tr. 1404]. The commission rate for all other SLC products is 3%. [Tr. 1404-05].

29. Mr. Merlau credibly testified that the Respondent has never been notified by the DEA that any of its SLC products, specifically Double Action, has been found at an illicit methamphetamine laboratory. [Tr. 657-57 [sic]]. Based on that, the Respondent does not believe that it and its business practices are part of the illicit methamphetamine production problem. [Tr. 658].

2. Warehouse Employees' Handling of SLC Product

30. When the Respondent's corporate office authorizes the shipment of SLC product to a particular sales representative, corporate office officials do not know what quantity of SLC product is going to which particular convenience store. [Tr. 633]. Only the sales representative has that information at the time of shipment from the warehouse. [Tr. 633, 1426-27].

31. The Respondent's warehouse segregates its SLC products from its other merchandise, placing its SLC in a locked, caged area of the warehouse. [Tr. 131-32, 1521; Resp. Exh. 13]. The cage area is a restricted access area, for not everyone of the Respondent's employees have access to that area of the warehouse. [Tr. 2288-89]. Only authorized employees are allowed access to the caged SLC product's storage facility within the warehouse. To receive the

Respondent's authority to access the caged storage area, warehouse employees must pass criminal background checks and undergo specific training at the Respondent's registered location on cage procedures and the legal requirements for handling SLC products. [Tr. 132, 2278-79; Resp. Exh. 10, 13]. The Respondent has conducted background checks on everyone who has access to the cage. [Tr. 132].

32. The cage is divided into two parts, separated by fencing. One part is for current inventory, and the second part is for SLC products for future shipment, or for sorting and return to the manufacturer. [Tr. 132, 1511-12, 1514-15, 2269-73; Resp. Exh. 11, 13].

3. Sales Representatives' Handling of SLC Product

33. Although not required by law or regulation, the Respondent limited its customers' purchases of SLC products to one case per transaction of each product type. [Tr. 100, 655]. The Respondent's sales representatives visit their customers on an average of twice a week. [Tr. 100-101]. Therefore, an individual customer may purchase up to two cases of a single SLC product per month. [Tr. 101]. Each product, or SKU, may be purchased up to this quantity limit as long as the threshold quantities of sales of SLC products set by the CMEA are not exceeded. [Tr. 103-04, 556, 622, 624]. The Respondent sells more than 10 different SLC products. [Tr. 623]. Regarding quantities in a case, one case generally contains 144 store-keeping units. [Tr. 621-23].

34. Mr. Merlau credibly testified that the Respondent limited its sale of SLC products as a conscientious effort to eliminate any risk of diversion. [Tr. 620; *see also Tr.* 1291-92].

35. Should the sales representative sell more than one case of a particular SLC product during any single transaction, Mr. Green credibly testified that he would "cut them off, stop the sale of product to them." [Tr. 159]. Mr. Bledsoe further stated that such actions by a sales representative would result in that person being given a written reprimand for the first such occurrence, and such person may be terminated from his position if such a sale happens a second time. [Tr. 1310-11, 1434-36; Resp. Exh. 38].

36. The record contains a summary prepared by DI Barnhill of sales data provided by the Respondent. [Tr. 1496-1506; Govt. Exh. 68]. This summary indicates that, between January and July of 2007, sales transactions over the one case limit occurred 85 times. [Govt. Exh. 68].[4]

37. Upon receipt of the SLC product at the "drop off point," the sales representative uses the warehouse's load sheet to ensure the accuracy of the

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[4] Mr. Bledsoe testified that, between January of 2007, and January of 2008, such unauthorized sales over the one case limit happened approximately 35 to 45 times out of approximately 100,000 to 130,000 sales transactions. [Tr. 1440]. Yet I find DI Barnhill's summary more credible, as it is actually based upon the Respondent's records rather than Mr. Bledsoe's memory.

shipment. The sales representatives are directed to place the SLC products, upon delivery to the drop-off point, immediately into their delivery vans. [Tr. 2293-94; Resp. Exh. 28 at 60]. After verifying the shipment, the sales representative returns the load sheet to headquarters. [Tr. 687-88]. In the event the products delivered do not match the load sheet, the sales representative is to call the transportation section at headquarters for investigation of the discrepancy. [Tr. 689-90].

38. In handling store returns of listed chemical products, a salesperson may retrieve the product from the retailer and issue a credit to that retailer. [Tr. 1309]. If the product is undamaged, and selling the product in that salesperson's territory would not violate any state or federal laws or regulations, the salesperson may enter the product into his or her inventory and resell it to a customer on the sales route. [Tr. 1309]. In cases where returned product is resold, it is not first sent back to the Respondent's registered warehouse. [Tr. 1309-10; Resp. Exh. 10].

39. The sales representatives determine the quantities of SLC products to order for each customer based on the sales history of that customer for that product. [Tr. 1282, 1421-22]. Then the sales representative places the order on the customer's behalf with the Respondent. [Tr. 128, 1299-1301]. The store's manager would agree or confirm the order. [Tr. 134, 630]. The sales representatives also count the on-hand SLC products with the store manager to ensure accurate inventory.

40. Next, the sales representative refills the cabinet where the SLC products are maintained and checks to ensure the store's logbook is being used. [Tr. 144]. The lockable cabinet was supplied by the Respondent to all of its customers. It will hold approximately 18 to 22 boxes of the 24-count SLC product. [Tr. 1422]. The cabinet would also hold three "sleeves" of SLC products. [Tr. 1422-23]. A sleeve of 6-count SLC products and a sleeve of 12-count SLC products would contain 24 such packages. [Tr. 1422-23].

41. A convenience store receives an invoice at the time the SLC product is delivered to the store. [Tr. 630-31]. The store's manager signs the invoice after confirming the delivery of the products. [Tr. 688]. The sales representative sends a paper copy of the invoice to headquarters. [Tr. 688]. The Respondent's corporate office maintains all of the required records for SLC products. [Tr. 632-35].

4. DMD Incident

According to a DMD employee, in September of 2002, DMD, a supplier of the Respondent's at the time, shipped an entire lot of combination ephedrine products to the Respondent. [Tr. 1079]. In November of 2002, 22 bottles of 60-count, 25 mg ephedrine product from this lot were discovered in an illicit methamphetamine lab in Thompson, Connecticut. [Tr. 1077]. DMD received a warning letter concerning this diverted product. [Tr. 1077-1079]. The Respondent's

personnel, however, were not told by the DEA that these products had been found in an illicit methamphetamine lab. [Tr. 1526-27, 2261-2263].

43. In early 2003, DMD informed the Respondent of this event and met with the Respondent's personnel to "review procedures, education, (and) security." [Tr. 1080]. The Respondent had tracked the shipment of this product to two of its sales representatives in New England. [Tr. 1526, 2259-60]. However, the Respondent could not determine what specific stores ultimately received this product. [Tr. 1526-27].

44. The Respondent checked with Novelty sales representatives concerning that area as well as surrounding retail locations to inquire about any suspicious List 1 activities. [Tr. 1079-80].

45. Subsequently, the Respondent's personnel talk with DI Kuzma and informed her that three cases of the lot numbered product in question had been delivered to the Respondent's sales representatives, but the Respondent had no way to identify what specific retail locations received the SLC products from these lots. [Tr. 1083-84]. These personnel were cooperative with DI Kuzma and worked, as best they could, to identify the distribution chain for the lot-numbered product. [Tr. 1103-04].[5] DI Kuzma did

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[5] The record contains no further information about DMD and these 22 bottles of SLC product. [*See* Resp. Brief at 34-37 for

(Continued on following page)

not recommend to the Respondent that it cease selling SLC products in Connecticut or that it change its SLC product distribution procedures at that time. [Tr. 1101-02].

46. The Respondent still has a working relationship with DMD. [Tr. 1516]. DMD is located in central Indiana, approximately 50 miles from the Respondent. [Tr. 1516-17].

5. Post-Immediate Suspension SLC Handling Options

47. After the Respondent's authority to handle SLC was immediately suspended by the DEA, Mr. Bledsoe and Mr. Merlau explored the possibility of Respondent's employees working as sales agents for another SLC product distributor, BDI. [Tr. 2361-62; Govt. Exh. 48]. Mr. Green signed a letter dated February 8, 2008, informing his SLC-product customers of the company's inquiry into a proposed sales arrangement between the convenience store, the Respondent, and BDI, a distributor of SLC products. [Tr. 2401-03; Govt. Exh. 48].

48. However, BDI refused to enter into this sales arrangement, and the proposed sales relationships were not completed. [Tr. 2403]. The Respondent's personnel are still exploring ways to sell SLC

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a review of the evidence not found in this record regarding this incident.].

products to their convenience store customers without actually handling the SLC product. The shipment of the product would be from the manufacturer directly to the Respondent's customers. [Tr. 2403]. But no such agreements existed at the time of the hearing. [Tr. 2403].

C. *Respondent's Shipping Model*

49. The Respondent ships all products, to include SLC products, on its own trucks, using leased trailers. [Tr. 693]. The truck drivers are the Respondent's employees. [Tr. 693]. The Respondent's trucks go from its registered location to approximately 150 various self-storage facilities ("drop off points") throughout the country. [Tr. 1281-82]. The Respondent's truck drivers make deliveries to the drop off points one time per week. [Tr. 77]. The Respondent's dispatcher calls the sales representatives and tells them what time the delivery is expected at the drop off point. [Tr. 77]. Depending on the sales representative's route, the delivered products may stay in the drop off facility for up to a few days before the sales representative returned to the drop off point to reload his delivery truck. [Tr. 534]. However, the average time at the drop off point is usually measured in hours, up to 48 hours. [Tr. 1273, 1282-83, 1301-04, 2346-48].

50. At the drop off point, the Respondent's sales representatives load a smaller truck and deliver the products to the individual customers on their routes.

[Tr. 73-76, 530, 556-57, 682-83, 693]. Each sales representative has approximately 80 stores to whom he or she sells the Respondent's products. [Tr. 134, 1282].

51. Then the product may remain on the sales representatives' trucks for many calendar days. For example, if a sales representative loads his delivery truck on a Saturday, and it contains product to be delivered to a convenience store the following Friday, the truck may stay loaded with product, to include SLC product, for several days. The truck is often padlocked. [Tr. 537-38].

52. None of the drop off point facilities is registered with the DEA. [Tr. 1284].

53. When SLC products leave the Respondent's registered location, the Respondent does not know which specific convenience store will receive the SLC products in that shipment. [Tr. 2082]. The Respondent's shipping records only identify which products and which lot numbers of those products are shipped to which route and sales representative. [Tr. 1517].

54. The drop off points are individual storage units located in self-storage type facilities. They are locked with a padlock provided by the Respondent, and the Respondent's truck drivers, the district managers for the sales representatives, and the sales representatives have a key to the padlock. [Tr. 76, 128-29, 531, 535-36]. The keys may not be duplicated. [Tr. 535]. However, the district managers also have keys that would open any of the Respondents' padlocks.

[Tr. 536]. The drop off point units do not have separate cages for the storage of SLC products. [Tr. 132-33, 538-39].

55. The drop off storage units have varying degrees of additional physical security, ranging from fenced areas with cameras and limited coded access points to, in at least one instance, no external security around the entire self-storage facility. Anyone could directly access the padlocked, sales representative's storage unit in the latter example. [Tr. 131, 538].

56. The SLC products were often delivered in a green tote that had a zip tie securing the tote [Tr. 539]. The zip tie would have to be cut off the tote to access the products inside. [Tr. 539-40]. The sales representative would know if the tote had been tampered with prior to his or her arrival. [Tr. 539-40].

57. The Respondent views this shipping process as being a major reason why it is so successful. Specifically, in selling its program to the convenience store chains, the Respondent represents that it controls all of the parts of the manufacturer-to-market delivery. The Respondent uses its own trucks, its own warehouse, its own sales representatives, and, in the case of novelties, distributes its own products. This marketing process provides the Respondent with control over all segments of its distribution, thereby providing it with the ability to control the quality of the products and services offered to its customers. [Tr. 644]. For that reason, the Respondent

does not use a commercial mode of shipping, such as Federal Express or UPS. By using such a commercial shipper, the Respondent would lose control over its products and its delivery systems. [Tr. 644-45].

58. The Respondent also views this shipping process as being more secure when distributing SLC products. Mr. Merlau credibly explained that, when using a commercial carrier, the Respondent had no control over where the products went within the shipping system. It also had no control over how long its products sat in transit. By controlling these factors, the Respondent believed, it controlled access to SLC products in route to only its own employees. [Tr. 645]. Specifically, Mr. Merlau opined: "We view that what we have is much tighter and a more controlled and better process than anything out there." [Tr. 645].

59. In some instances, however, when the Respondent ships samples of product to its sales representatives, or ships a missed product order, the Respondent may use a commercial carrier like Federal Express or UPS. But such instances are rare. [Tr. 695].

60. In May of 2004, the DEA, in a letter written by Group Supervisor Raber, ("Raber letter"), informed the Respondent of situations when an exception may apply to the registration requirement for all distribution points for a SLC distributor. However, the Respondent's transportation system did not meet the criteria established in the letter. [Tr. 1321-23; Govt.

Exh. 100]. The Respondent understood this letter to mean that the Respondent would have to register each of its "drop off" points. [See Govt. Exh. 100]

61. The Respondent disagrees with the DEA's position, and asserts it is not storing SLC products in unregistered locations. [Tr. 666-67]. Rather, the Respondent views its use of the "drop off points" as part of its transportation system, not its storage system. [Tr. 668-70].

62. When it received this letter, the Respondent had it reviewed by its in-house counsel. Upon advice of counsel, the Respondent sought a declaratory judgment from the federal district court concerning the legality of the DEA's interpretation of its regulations as they relate to the Respondent's business model. [Tr. 646-49, 1377, 1381]. The Respondent did not alter its business practices pending the court's decision. [Tr. 665, 1323, 1381, 1418]. Further, the Respondent did not call anyone at DEA Headquarters to verify the validity of the contents of the letter. [Tr. 1435].

63. Specifically, Mr. Merlau credibly testified:

> This was a letter that was issued by a supervisor, not policy, not law. If it makes sense, we will, of course, follow it. If it doesn't make sense, it's not presented as the law or the regulation and that's why we went to Court.
>
> Not to be argumentative or not follow the rules, but to seek clarity of what they are, and it's really all about trying to make sure

> that we do what's the right thing which is control this product.

[Tr. 653].

64. Although aware of this disagreement in interpretation, the DEA continued to renew the Respondent's registration in 2005 and 2006. [See Tr. 1319-21].

65. At the hearing, Mr. Bledsoe credibly testified that, should the DEA's final order[6] instruct the Respondent to change its shipping methods or DEA registrations, the Respondent would comply with such directions. [Tr. 1400-01, 1412-13].

D. *Respondent's Customers*

66. The sale of SLC products represents about 10 to 15% of the Respondent's overall gross sales. [Tr. 558-59]. Yet the record contains evidence from the Respondent's sales invoices retrieved from the Respondent's convenience store customers of instances where convenience stores purchased SLC products from the Respondent in percentages greater than 50% of the overall purchases made by that store in any given transaction. [Tr. 1455-59; Govt. Exh. 38].

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[6] Although Mr. Bledsoe testified in terms of "this court" ordering the Respondent's shipping practices be altered, I am interpreting this testimony to mean that, should the DEA in a final order dictate such a change in practice. Bledsoe stated that Respondent would comply.

67. The Respondent contracts with parent companies of large, chain convenience stores, to supply goods and SLC products directly to the stores owned by the parent companies. [Tr. 145-46]. The convenience stores sell the products directly to consumers. [Tr. 143]. The Respondent considers a company a chain of convenience stores if they have 10 stores or more. [Tr. 2356].

68. The Respondent's convenience store customers are self-certified, in compliance with the requirements of the CMEA. [Tr. 1332; Resp. Exhs 57, 57A]. The Respondent's personnel work with the convenience stores to assist them in getting their employees self-certified. [Tr. 1333-37, 1363-69, 1381; Resp. Exhs. 44]. In the Fall of 2006, the Respondent created a DVD to assist in this training program. [Tr. 1382-92; Resp. Exh. 48]. A retailer with in excess of 10 locations may begin to handle SLC products after submitting the required self-certification information on a CD to the DEA. "The DEA does not require that the retailer receive actual hard copies of the self-certification certificate before the retailer is permitted to sell schedule listed chemical products." [Tr. 1334-35].

69. Yet, the DEA does not list for public knowledge, all of the self-certified retailers. [Tr. 1335]. In order to determine whether a retail outlet is self-certified, the Respondent goes to the retail outlet itself to determine the certification status. [Tr. 1340].

70. When the Respondent's headquarters' staff is informed of the self-certification of a customer, a staff member will transmit this information to the sales person through either the Respondent's weekly newsletter or by use of the company voice mail system. [Tr. 1431-32].

71. Although mentioned in the Order to Show Cause to the contrary, I find that the 35 stores listed as not being self-certified, were, in fact, self-certified at the time the Respondent sold them listed chemical products. [Tr. 1337-40]. Mr. Bledsoe credibly testified, however, that some of the addresses on the self certification forms in the Respondent's records did not match the addresses on the distribution records or sales records for those business entities. [Tr. 1407-08].

72. The Respondent provides its convenience store customers with a lockable, plexiglass cabinet to be used to store SLC products behind the counter, in compliance with the requirements established by the CMEA. The containers also display stickers provided by the Respondent that remind the convenience store personnel and their customers of the sales limitations. These limitations include the sale of only two SLC products to a given customer during a given transaction. The stickers also inform personnel about the test to use to determine if a suspicious sale is being attempted by a customer. [Tr. 1390; Resp. Exh. 34].

73. The Respondent provided the DEA with a list of its customers. [Tr. 2236-37].

1. Tennessee Stores

74. As part of the DEA's investigation, DI McGee visited some of the Respondent's convenience store customers in Tennessee. [Tr. 707-08]. First, on August 29, 2007, DI McGee visited a Roadrunner Market in Kingsport, Tennessee, identified as Store Number 110. [Tr. 708]. DI McGee also visited a Roadrunner Store in Gray, Tennessee, Store Number 139, and one in Bristol, Tennessee, Store Number 117.

75. At Store Number 110, DI McGee spoke with the store's manager, Ms. Smith, who had worked at the store for approximately 2 years. [Tr. 710-11]. She confirmed that the store sold ephedrine products, Double Action, and that the Respondent was the only supplier of ephedrine products for that store. [Tr. 711-13]. The Respondent's sales representative visited the store about one time per month. [Tr. 711]. The store sold a 24-count box of 25mg ephedrine combination product at retail for $9.99. [Tr. 711].

76. In March of 2008, DI McGee obtained an invoice from Store 110, dated January 23, 2008, recording a sale of 24 Double Action 12.5 mg, 24-count boxes. [Govt. Exh. 79 at 3].

77. Also on August 29, 2007, DI McGee visited a Roadrunner Market in Gray, Tennessee, Store Number 139, and spoke with an assistant manager, Ms. Herad, and a regional manager, Mr. Kelly, who happened to be in the store at that time. [Tr. 714-15]. Ms. Herad had worked for the company for approximately seven to eight years, and had been in a

management position for approximately three to four years. [Tr. 716]. This store also sold ephedrine products distributed by the Respondent, and received shipments every other week. [Tr. 717-18]. This store received six boxes of 24-count Double Action every other week. [Tr. 717-18]. The retail price for this product was $9.99. [Tr. 718]. For approximately the past two years, the Respondent has been its only source for ephedrine products. [Tr. 718].

78. However, in March of 2008, DI McGee retrieved an invoice dated January 24, 2008, documenting a sale of 72 Double Action 12.5 mg, 24-count gel caps to Store 139. [Govt. Exh. 79 at 2].

79. DI McGee also reviewed log books from the Gray, Tennessee store and prepared a summary of repetitive purchasers. [Tr. 728, 731-32; Govt. Exh. 80].

80. Lastly, on the same date, DI McGee visited a Roadrunner Market in Bristol, Tennessee, Store Number 117. [Tr. 720-21]. He met with the manager of the store, who had been with Roadrunner Market for 14 years. [Tr. 721]. For approximately two to three years, the Respondent has been this store's sole distributor of ephedrine products. [Tr. 721]. Twice a month, the Respondent's sales representative delivers 60 packets of 24-count Double Action ephedrine product. [Tr. 723]. The store sells the packet for $9.99. [Tr. 723]. However, DI McGee obtained an invoice from the Respondent to this store dated January 19, 2008, indicating that the Respondent sold this store

144 boxes of 24-count Double Action 25mg ephedrine product. [Govt. Exh. 79].

81. After reviewing the customer log books[7] from Store 117, DI McGee prepared a summary of significant entries recorded between July 23 and August 23 of 2007. [Tr. 725-26; Govt. Exh. 46]. He was searching for customers who made repetitive purchases of ephedrine product. [Tr. 730, 733]. He found the sales to three specific customers, MW, CM, and EB, noteworthy, for during the one month period, MW bought 56 boxes or 1,344 gel caps. On at least four occasions, MW visited the store twice in one day, buying two boxes on each visit. The total amount of ephedrine sold to MW exceeded the thirty-day, 9 gram limit of 439 gel caps. [Govt. Exh. 46]. In the same time frame, CM purchased 23 boxes, totaling 552 gel caps, and EB purchased 52 boxes, totaling 1,248 gel caps, all above the 9 gram, 439 gel cap 30-day limit. [Govt. Exh. 46]. Yet, the record contains no evidence that the DEA conducted any further investigation regarding these purchases and the uses these individuals made of the SLC products purchased. [Tr. 753-54, 771-72, 1089-93].[8]

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[7] The parties do not dispute that the Respondent is not lawfully authorized to review any of the content of the stores' logbooks.

[8] Government Exhibit 80 also shows repeat purchases for customers RB and BL at Store 117; RB, BL, and CB at Store 110; and RB and CB, at Store 139. However, the exhibit does not show the count or strength of the product purchased. DI McGee

(Continued on following page)

82. At each store, logbook entries would be made by the cashier at the time of purchase of the ephedrine product. [Tr. 756].

83. DI McGee did not receive any other store data that confirmed the sales listed in the log books actually occurred. [Tr. 756].

2. New York Stores

84. In September of 2007, DEA Group Supervisor ("GS") Gillen visited the Smoker Friendly No. 4 convenience store in Little Falls, New York. [Tr. 785-86]. GS Gillen spoke with the store's manager, who had worked at the store for approximately two years. [Tr. 787]. Approximately every two weeks, a sales representative from the Respondent sells SLC products to this store by refilling the locked acrylic case used to store these products. [Tr. 788-89, 823]. At retail, this store sold the 24-count 12.5 mg ephedrine product for $10.99, and the six-count package at a retail price of $3.99. [Tr. 789].

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was shown a package of 24 count, 25 mg ephedrine product by a store personnel in Store 110. I have no basis to assume that between 2006 and 2008 this product was the only count and strength ephedrine product sold at these locations. [Tr. 711-713]. The Government, in its post-hearing brief, made assumptions as to quantities and strengths purchased. [Govt. Brief at 18]. I chose not to make such assumptions. Therefore, I could not make any further factual findings regarding these purchases. [Govt. Exh. 80 at 1].

85. GS Gillen also obtained a log book from the store. [Tr. 791-92]. The entries were made by various employees on duty when the product was purchased and by the purchaser at the time of the sale. [Tr. 822]. The logbook also had the follow [sic] statement stamped at the top of each page:

> Company policy limits the sale of ephedrine products to two packages per transaction and one transaction per day.

[Tr. 825-26].

86. Lisa Barnhill reviewed a summary of the purchases and purchasers who made repetitive purchases of ephedrine product from this store. [Tr. 791-93, 1475-76; Govt. Exh. 45]. From July 27, 2007, through August 27, 2007, one purchaser made 21 purchases, for a total of 984, 25mg dosage units, or about 24.6 grams. A second person made 19 purchases, for a total of 768, 25mg dosage units, or about 19.2 grams; a third person made 13 purchases for a total of 600, 25mg dosage units, or about 15 grams; and a fourth person made 18 purchases for a total of 696, 25 mg dosage units, or about 17.4 grams. The last two listed purchasers listed the same address in the logbook. [Govt. Exh. 45]. However, the record contains no evidence that the DEA took any additional action regarding these purchasers.

87. The employees at Smoker Friendly were self-certified in compliance with the CMEA. [Tr. 828].

88. On September 5, 2007, GS Gillen also visited J & R Stop and Shop in Endicott, New York, and met with the store's manager. [Tr. 799-800]. The manager had worked at this store for approximately six years. [Tr. 800]. Three months prior to GS Gillen's visit, this store changed its supplier for SLC products. However, for approximately seven years prior to that, the Respondent supplied this store with ephedrine products. [Tr. 801-02]. The store sold the 24-count, 12.5 mg ephedrine-based products for $11.99, and $12.99 for the 24-count, 25 mg ephedrine products. [Tr. 802]. Approximately two times a month, the Respondent's sales representative would refill the acrylic display case with the SLC products. [Tr. 802-03].

89. The employees were self-certified, and the manager remained current in ephedrine issues. [Tr. 831]. The SLC products were kept in an acrylic box like the one from Smokers Friendly. [Tr. 831-32].

90. The employee at J & R Stop and Shop confirmed that log books were being utilized, and that each page contained the same limitation of product sales as the log books reviewed by DEA personnel at Smoker Friendly. [Tr. 832-33]. The diversion investigator found no evidence that any of J&R's employees failed to comply with the sales limitation requirements for the sale of listed chemical products. [Tr. 833].

91. GS Dale Shick visited the Mason of New York convenience store in Jamestown, New York, in

September of 2007. [Tr. 808-09]. For approximately five years, the Respondent, as a sole provider, supplied this store with ephedrine-based products. [Tr. 814-15]. Approximately every two weeks, the Respondent's sales representative would restock the store's acrylic case containing the ephedrine products. [Tr. 815-16]. The store purchased Double Action 24-count package of 12.5 mg of ephedrine, selling for $11.29 per box at retail; Ephedrine Plus, a 6-count, 25 mg ephedrine product, selling at $11.29 per box; and Mini Ephedrine, a 24-count, 12.5 mg ephedrine product, selling at $11.29 per box. [Tr. 816].

92. After reviewing logbooks from this store, DI Barnhill summarized the purchases of SLC products by 10 individuals between July 21 and August 21, 2007. [Tr. 1482-84]. These purchases ranged from 360 dosage units to 1,548 dosage units. [Tr. 1482-84; Govt. Exh. 49]. Five customers purchased over 1,000 tablets each, which, if in the lower 12.5 mg strength, would exceed the 9 gram, 30-day purchase limit. [Govt. Exh. 49].

93. DI Gelin visited the Daily Mart in Watervliet, New York, on August 31, 2007. [Tr. 992-93]. She spoke with Mr. Sadiq, who had been the store manager for approximately one year. [Tr. 993]. Daily Mart purchased ephedrine products from only the Respondent, who had been its supplier for the past several years. [Tr. 994-95]. The sales representative determined the amount of ephedrine to restock, and he came to the store every two weeks. [Tr. 994-95].

Generally, the store spent approximately $792.00 per month on ephedrine products, to include Ephedrine Plus, 25 mg, 24-count box, which sold at retail for $11.99 a box, and Double Action ephedrine, 12.5 mg, 24-count box, which sold at retail for $10.99 a box. [Tr. 995-96]. The SLC products were displayed behind the counter in a locked plexiglass container. [Tr. 1021-22]. The Daily Mart was self-certified, and Mr. Sadiq had received some training materials from the Respondent. [Tr. 1024].

94. In September of 2007, DI Gelen [sic] also called a CVS Pharmacy in Little Falls, New York, and spoke to Ms. Daniels, a pharmacist. [Tr. 998-99]. This CVS carried ephedrine products, Primatene tablets and Bronchaid tablets. [Tr. 999, 1025-26]. DI Gelen [sic] obtained a logbook from Ms. Daniels after her visit. [Tr. 1,000; Govt. Exh. 28]. The logbook indicated that between February and September of 2007, this pharmacy sold 328 packages of pseudoephedrine product and 95 packages of ephedrine product. The same purchaser purchased 85 packages of the ephedrine sold during this timeframe. [Tr. 1475-76; Govt. Exh. 28].

95. Also in September of 2007, DI Gelin [sic] contacted Ms. Caruso, a pharmacist for Kinney Drugs in Little Falls, New York. [Tr. 1001]. Ms. Caruso confirmed that Kinney Drugs did not carry any ephedrine tablet products. [Tr. 1002].

96. In August of 2007, DI Gellin [sic] also called a CVS Pharmacy in Endicott, New York, speaking to

Mr. Sanford, the supervising pharmacist. [Tr. 1002-03]. This CVS carries Primatene tablets. [Tr. 1003]. In November of 2007, DI Gellin [sic] received logbooks from this CVS Pharmacy. [Tr. 1003-04, 1469-70; Govt. Exh. 26A; *see summary* Govt. Exh. 26].

97. In August of 2007, DI Gellin [sic] also called P.J. Colella Pharmacy in Endicott, New York, speaking to supervising pharmacist McGee. [Tr. 1004-05]. This pharmacy does not carry any ephedrine tablet products. [Tr. 1005].

98. Also in August of 2007, DI Gellin [sic] called a second CVS Pharmacy in Endicott, New York, speaking to Mr. Isaac, the pharmacist. [Tr. 1006]. This pharmacy carries ephedrine products, Primatene tablets and Bronchaid tablets. [Tr. 1007, 1034].

99. Also in August of 2007, DI Gellin [sic] contacted a pharmacy in Watervliet, New York, speaking to Ms. Derby, a part-time pharmacist. [Tr. 1007-08]. This pharmacy does not carry any ephedrine products. [Tr. 1008].

100. DI Gellin [sic] also contacted the Hannaford Supermarket and Pharmacy in Latham, New York, in August of 2007, speaking to the supervising pharmacist, Mr. Adams. [Tr. 1009-10]. Mr. Adams stated that the store carries Primatene Mist and Primatene tablets, both ephedrine-containing products. [Tr. 1010-11].

101. DI Gellin [sic] also obtained a logbook from Hannaford, which indicated that Primatene tablets,

12.5 mg, 60-count sold for $8.99. [Tr. 1011-12]. Hannaford kept two to three such boxes in its inventory. [Tr. 1012]. A summary was prepared of the logbook entries, and, after minor corrections made during the hearing, the summary reflected that from March to September of 2007, the store sold 639 boxes of pesudoephedrine [sic] product, 16 boxes of ephedrine product, and 6 containers of ephedrine mist. [Tr. 1472- 74; Govt. Exh. 27].

102. In August of 2007, DI Gellin [sic] also contacted a Rite Aid Pharmacy in Watervliet, New York, speaking to Ms. Bordeaux, a pharmacist. [Tr. 1013-14]. She received a logbook of SLC product sales from this pharmacy. [Tr. 1015-16; Govt. Exh. 29B]. Between April 25 and October 12, 2007, this store sold 295 packages of pseudoephedrine products, and 16 ephedrine products. [Tr. 1476-79; Govt. Exh. 29].

3. Pennsylvania Stores

103. On August 28, 2007, DI Colosimo visited the CoGo's Company Convenience Store in Belle Vernon, Pennsylvania. [Tr. 848-49]. He interviewed Mr. Donas, the Director of Operations for the Western Pennsylvania Region for CoGo's Stores. [Tr. 849-50].

104. The Belle Vernon store had purchased combination ephedrine products from the Respondent. [Tr. 851-52]. Mr. Donas explained that the Respondent's driver would replenish the existing store stock at this store, as well as at other CoGo's in Western Pennsylvania, about every two weeks. [Tr.

852]. The Belle Vernon store carried the Ephedrine Plus, 12.5 mg, 24-count, selling at $12.99 per package, the Double Action ephedrine 25 mg, 6-count, selling at retail for $2.99, and the Mini Ephedrine two-way tablets in the 25 mg, 6-count, selling for $3.99. [Tr. 852-53]. Mr. Donas believed these products were purchased by truck drivers or nurses to help them stay awake or alert on their jobs. [Tr. 853, 886-87]. The products were behind the counter in an acrylic display case. [Tr. 882-83].

105. DI Colosimo also received and reviewed logbooks from the CoGo's in Belle Vernon. He credibly testified that he did not see any instances where a customer purchased more than two packages of SLC product during a single visit. [Tr. 885].

106. DI Colosimo also received portions of log books from a CoGo in Somerset, Pennsylvania. [Tr. 860-61; Govt. Exh. 75]. After reviewing the logbooks, DI Colosimo discovered that from August 16, 2007, to August 23, 2007, a customer (SM) purchased 384 dosage units of ephedrine product. [Govt. Exh. 75]. Consistent with a DEA table converting dosage units into weights, if these were 12.5 mg product, then these purchases would equal 4.8 grams in this one week period. [Govt. Exh. 75; Tr. 826]. In addition, SM purchased 24-count boxes on four consecutive days, August 16 through August 19 of 2007. [Govt. Exh. 75].

107. On September 25, 2007, DI Colosimo visited two pharmacies in the Belle Vernon, Pennsylvania region. [Tr. 861]. At the first pharmacy, he asked the pharmacist if the store carried ephedrine products, and he was told it did not. [Tr. 863]. At the second pharmacy, DI Colosimo also discovered that it did not carry any ephedrine products. [Tr. 863-64]. Here, the pharmacist explained that there was no demand for the ephedrine products. [Tr. 865-66].

108. In March of 2008, DI Colosimo telephoned a Giant Eagle Pharmacy and Grocery Store and spoke to the pharmacy manager, who relayed that this store did not carry any ephedrine products. [Tr. 866-67].

109. On August 29, 2007, DI Colosimo visited Jacobs Petroleum Main Street in Uniontown, Pennsylvania. [Tr. 867-68, 888]. He spoke with two individuals, a part owner of Jacobs Petroleum and the Director of Retail Operations for Jacobs Petroleum, both officers over the six stores. [Tr. 868]. Two of the six stores carried SLC, combination ephedrine products, one of which was the store in Uniontown, Pennsylvania. [Tr. 869]. Specifically, the store carried Ephedrine Plus 12.5 mg, 24-count, selling for $12.99; Double Action 12.5 mg, 24-count, selling for $10.99, and Double Action 25 mg, 6-count, selling for $2.99. [Tr. 871]. Once every three weeks, one of the Respondent's sales representatives would replenish the stock. [Tr. 870]. The product was displayed in a plexiglass cabinet behind the counter. [Tr. 889].

110. The manager of this store was also present and commented on her customers who purchased the SLC products. Specifically she stated that they were primarily hospital employees of the Uniontown Hospital, which was located less than a mile from the store, who bought the product to stay alert and awake for their jobs. [Tr. 872-73]. She also stated that the store had a two package per day limit on the quantity of SLC products that could be purchased. [Tr. 873]. DI Colosimo credibly testified that he did not recall seeing any instances where customers purchased more than that limit per day. [Tr. 889-90].

111. The employees at Jacob's Petroleum had received training materials, which included a video, from Novelty, teaching them how to lawfully handle SLC products. [Tr. 890-91]. Their stores were self-certified. [Tr. 891].

112. In September of 2007, DI Colosimo also talked to three pharmacists in Uniontown. The pharmacist from Medicine Shoppe indicated that his pharmacy did not sell any ephedrine products, a second pharmacist from Walgreens, indicated that he did sell an ephedrine product, Primatene tablets, in a box of 60 tablets for $10.99, and a third pharmacist from CVS, stated that he carried Primatene tablets, 12.5 mg, 24-count for $4.99. [Tr. 873-877, 892-97]. The Primatene tablets were located behind the pharmacy counter. [Tr. 879]. The Primatene tablets were the only ephedrine-containing product carried at these two pharmacies. [Tr. 879].

113. On August 27, 2007, DI Tomei visited B.P. State Line Travel Center and Truck Stop ("State Line") in West Springfield, Pennsylvania. [Tr. 945]. He spoke with Mr. Singh, part owner of the store since April 5, 2005. [Tr. 945-46]. The store sells combined ephedrine products, located behind the counter and supplied by the Respondent approximately once a month. [Tr. 946-47, 960]. The Respondent's sales representative would restock the display case with the ephedrine products, which amounted to one case of SLC product a month. [Tr. 947]. State Line purchased the Double Action, 25 mg strength, 24-count ephedrine product, with a retail price of $9.99. [Tr. 948].

114. State Line and its employees were self-certified. [Tr. 961-62].

115. DI Tomei also received State Line's logbook. [Tr. 949; Govt. Exh. 82A]. He did not find any evidence that there were any purchases in a single visit by a single customer in excess of the 3.6 gram limitation, or any purchases in a 30-day period that exceeded the 9 gram limit. [Tr. 961; Govt. Exh. 82].

116. On August 28, 2007, DI Tomei visited a CoGo's convenience store in Midland, Pennsylvania. He spoke with Ms. Gillespie, the store's manager for the past seven years. [Tr. 950-51]. She purchased ephedrine products from the Respondent, approximately one case a month, to include the 24-count Double Action 12.5 mg, selling at retail for $12.99. [Tr. 951-52, 968]. The products were maintained

behind the counter. [Tr. 963]. All of the cashiers were self-certified. [Tr. 964].

117. DI Tomei also made a copy of CoGo's logbook. [Tr. 953]. He did not find evidence of any purchases over the allowed 3.6 gram daily limit, or the 9 gram 30-day limit. [Tr. 963-64; Govt. Exh. 41, 83]. However, one customer, between May 1 and May 31, 2007, purchased 620 dosage units of ephedrine product, and between June 1 and June 15, 2007, purchased 636 dosage units of ephedrine product. [Tr. 1486; Govt. Exh. 41].

118. From the same store's logbook, DI Barnhill prepared an additional summary which demonstrated the following purchasing pattern of SLC products:

Individual 1:	November 2006	9 boxes[9]
	December 2006	15 or 16 boxes
	January 2007	10 boxes
	February 2007	6 boxes
	April	6 boxes
	June 2007	1 box

[9] The record provides no further information about the content of the boxes (i.e. number of dosage units or strength of the product).

Individual 2:	November 2006	5 packs[10]
		5 boxes
	December 2006	30 boxes
	January 2007	13 or 14 boxes
	February 2007	4 boxes
	March 2007	16 boxes
	April 2007	10-¼ boxes
	June 2007	6 boxes

[Tr. 1487-88; Govt. Exh. 83].

119. In October of 2007, DI Tomei also visited a Rite Aid Pharmacy in Midland, Pennsylvania, which had carried Primatene Mist in the past. [Tr. 954, 964]. It was self-certified. [Tr. 966]. He also visited Ernie's Pharmacy in Midland, which had also sold Primatene Mist in the past. [Tr. 955-56, 967].

120. DI Rogers visited a Sunoco convenience store in Ebensburg, Pennsylvania, in August of 2007. [Tr. 973]. Mr. Patel, the owner and manager of the store, told DI Rogers that he purchased ephedrine products "bi-weekly." A sales representative of the Respondent would replenish the stock as needed. [Tr. 975-76, 982]. Specifically, Mr. Patel sold Ephedrine,

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[10] The record provides no further information about the content of the packages (i.e. number of dosage units or strength of the product).

12.5 mg, 24-count at retail for $6.36, and Double Action, 12.5 mg, 24-count for $13.99, and Mini Ephedrine, 25 mg, 12-count, for $3.99. [Tr. 976]. The product was kept in a locked, plexiglass cabinet. [Tr. 984-85]. Mr. Patel confirmed that the store's employees were self-certified. [Tr. 987].

121. DI Rogers also telephoned two pharmacies in the vicinity of Ebensburg, Pennsylvania, a Rite Aid Pharmacy and a Tibbott's Pharmacy. [Tr. 977-78]. At Rite Aid, she spoke to Mr. Ramsey, the pharmacy manager for the previous seven years. [Tr. 978]. Mr. Ramsey stated that he did not sell any ephedrine products in the store. [Tr. 979]. At Tibbott's Pharmacy, DI Rogers spoke on the telephone to Ms. Sharbrogie, a staff pharmacist for approximately two years. [Tr. 979]. Ms. Sharbrogie also stated that she did not sell any ephedrine products. [Tr. 980].

4. Indiana Stores

122. The Circle K Corporation has an exclusive business relationship with the Respondent, indicating that the Respondent would be the sole source of SLC product for the entire chain. [Tr. 1114-15].

123. On September 6, 2007, DI Kuzma visited the Circle K convenience store in Camby, Indiana. [Tr. 1051; Govt. Exh. 59]. She contacted the store's manager, Ms. Gibson, who had served in that position for approximately 2 years. [Tr. 1053; Govt. Exh. 59 at 1]. After the visit, Ms. Gibson provided DI Kuzma with logbooks. [Tr. 1054-55]. DI Kuzma prepared a

summary of the logbooks, reviewing frequent customers purchasing SLC products. [Tr. 1056; Govt. Exh. 77B]. DI Kuzma credibly testified that she found no instance where a single customer purchased more than 3.6 grams of ephedrine SLC products in a single day. [Tr. 1086]. However, she did identify one purchaser, MG, who, between November 6 and December 9, 2006, made 21 visits, purchasing a total of 114 dosage units. DI Kuzma also noted that the logbook indicated two or three visits where the quantity purchased had not been recorded. [Govt. Exh. 77B]. Yet, DI Kuzma also credibly testified that neither she nor anyone from the DEA to her knowledge relayed this information to any of the Respondent's personnel. [Tr. 1089-90].

124. The SLC products were maintained behind the counter in a locked plexiglass container. [Tr. 1086-87]. The container displayed stickers advising the customers and employees that a sale was limited to two packages of SLC product. [Tr. 1087].

125. On September 6, 2007, DI Kuzma visited the Circle K convenience store in Franklin, Indiana. [Tr. 1057; Govt. Exh. 60]. DI Kuzma interviewed Assistant Manager McDonald and cashier Stocklin. [Tr. 1057]. The following day DI Kuzma telephonically interviewed the store's manager, Ms. Duke. [Tr. 1057]. Subsequently, DI Kuzma also obtained logbooks from this store. [Tr. 1059]. DI Kuzma prepared a summary of these logbooks, noting customers who frequently purchased SLC products. [Tr. 1060-61; Govt. Exh. 77B]. Specifically, DI Kuzma noted that a customer,

SW, visited the store 29 times between July 12, 2007, and September 14, 2007, purchasing 186 dosage units of 25 mg ephedrine product, and 24 dosage units of 12.5 mg ephedrine. [Govt. Exh. 77B]. Yet, DI Kuzma also credibly testified that neither she nor anyone from the DEA to her knowledge relayed this information to any of the Respondent's personnel. [Tr. 1090-91].

126. Further, after reviewing the logbooks, DI Kuzma noted that they contained no information indicating that any single individual purchased more than 3.6 grams of ephedrine containing product in a single day. [Tr. 1095].

127. At this store, the SLC products were displayed in a locked plexiglass case behind the counter and contained stickers advising of the limit of two packages of SLC product on a single visit. [Tr. 1094-95].

128. On August 30, 2007, DI Kuzma visited the Circle K convenience store in Madison, Indiana, interviewing Ms. Bailey, the store's manager, and Ms. Hatton, the store's cashier for the past three years. [Tr. 1061-62; Govt. Exh. 61]. DI Kuzma learned that this store purchased ephedrine products from the Respondent every two weeks, consistent with an arrangement between the Respondent and the Circle K Corporation. [Govt. Exh. 61]. The Respondent's sales representative restocks the display cabinet, and, for example, on August 29, 2007, the Respondent delivered one box of 24-count ephedrine product, and

four boxes of 6-count ephedrine product. [Govt. Exh. 61]. This store handles Ephedrine Plus, 12.5 mg, 6-count, selling for $4.99; Double Action 12.5 mg, 6-count, selling for $2.99; Ephedrine Plus 12.5 mg, 24-count, selling for $14.99; and Double Action 12.5 mg, 24-count, selling for $10.99. [Govt. Exh. 61]. Ms. Bailey related that her customers told her they purchased these products to stay awake or for breathing or allergy problems. [Govt. Exh. 61].

129. The SLC products were displayed behind the counter in a locked plexiglass case containing stickers noting the limit of two packages of SLC product per transaction. [Tr. 1098-99].

130. All of the employees have been self-certified to handle the SLC products. [Govt. Exh. 61].

131. DI Kuzma also reviewed log books from the Madison Circle K convenience store. [Tr. 1065-66]. She prepared a summary of those logbooks, noting customers who made frequent purchases of SLC products. [Govt. Exh. 77B]. DI Kuzma noted that one customer, CB, made 11 visits to the store between October 26, 2006, and November 26, 2006, purchasing 480 dosage units of ephedrine product.[11] CB also made 10 visits between May 1, 2007, and May 30, 2007, purchasing 384 dosage units of ephedrine product.

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[11] In her notes, DI Kuzma noted that these products were in the standard 12.5 mg and 25 mg strengths, but she did not record the breakdown of number of dosage units per milligram strength in her summary.

[Govt. Exh. 77B]. Yet, DI Kuzma also credibly testified that neither she nor anyone from the DEA to her knowledge relayed this information to any of the Respondent's personnel. [Tr. 1091-93]. Lastly, she credibly stated that the logbooks did not disclose any individual purchases of more than 3.6 grams of ephedrine. [Tr. 1098].

132. DI Kuzma also noted another customer, PE, who visited the Madison Circle K nine times between March 1, 2007, and March 31, 2007, and purchased 384 dosage units of "apparently 25 mg ephedrine" product. [Govt. Exh. 77B].

133. DI Kuzma also obtained purchase records for ephedrine products purchased from the Respondent by the three Circle K convenience stores in Franklin, Indiana, Camby Indiana, and Madison, Indiana. [Govt. Exh. 77].

134. The following SLC purchases were made at the Franklin store between December of 2006 and October of 2007, for a total of $8,656.83 retail price:

Count	Strength	Total Purchase
24	25 mg	328
24	12.5 mg	246
12	25 mg	240
12	12.5 mg	48
6	25 mg	407
6	12.5 mg	48

135. The following SLC purchases were made at the Camby store between November of 2006 and October of 2007, for a total of $21,605.21 retail price:

Count	Strength	Total Purchased
24	25 mg	462
24	12.5 mg	630
12	25 mg	456
12	12.5 mg	96
6	25 mg	1,391
6	12.5 mg	72
6	Unknown	72
2	Unknown	96
24	Pseudo. Unknown	168
12	Pseudo Unknown	288

136. The following SLC purchases were made at the Madison store between November of 2006 and October of 2007, for a total retail price of $22,254.18:[12]

Count	Strength	Total Purchased
24	25 mg	948
24	12.5 mg	690
12	25 mg	120
12	12.5 mg	96
6	25 mg	886
6	12.5 mg	192

[12] The Government provided a summary exhibit of frequent purchasers of ephedrine products from these three Circle K stores. However, none of the purchases exceeded the 9 gram, 30-day limit. [Govt. Exh. 77B; *see also* Govt. Brief at 20-21].

E. *Respondent's Recordkeeping Practices*

137. Prior to the Order to Show Cause in this matter, the Respondent never received any information from the DEA that the DEA had found the Respondent's recordkeeping inadequate or not in compliance with the DEA's regulations. [Tr. 662, 1421-22].

138. The Respondent produced documents regarding approximately 254,000 sales transactions that included SLC products during the requested time frame. Eight of these documents had typographical errors that created substantive recordkeeping mistakes. [Tr. 2396].

1. Erroneous Sale of Bottled SLC Product

139. Since the enactment of the CMEA, SLC products must be sold in blister packs and may no longer be sold in bottles. [Tr. 1448]. From the Respondent's records, the DEA prepared a summary of the Respondent's sales showing that the Respondent sold bottled SLC product after the enactment of the CMEA. [Tr. 1449-52; Govt. Exh. 37, 66].

140. Specifically, after the DEA's administrative inspection, the DEA discovered in the records provided by the Respondent, three sales of SLC products in bottles (Product number 17902) had occurred in 2007, after the enactment of the CMEA which prohibited such sales. [Tr. 1442-45; Govt. Exh. 37, 66].

141. Yet, according to additional records of the Respondent, the last date on which bottled product

(Product Number 17902) was shipped for delivery to convenience stores was January 16, 2006. [Tr. 2289-97; Resp. Exh. 40 at 152; *see also* Tr. 2393-97; *Resp.* Exh. 40 at 152]. Specifically, Mr. Bledsoe credibly testified that, after receiving the DEA's allegations, he ordered the investigation of the sales to the stores identified in the DEA's proffered exhibits for this proceeding. After reviewing the stores' scan data, Mr. Merlau confirmed that the erroneous product number did not occur in the scan data provided by these stores. From this information, Mr. Bledsoe testified that Novelty executives concluded the product item numbers in question were erroneously entered, and that the Respondent had not sold the illegal products to the convenience stores identified by the DEA. [Tr. 1417-20, 2289-91; Resp. Exh. 46; *see also* Tr. 1346-47, 2395].

142. Further, the sale of Product Number 17902 had been discontinued at least six months before the DEA's alleged illegal sales. [See Tr. 1346-47].

143. Thus, three of the Respondent's sales reports erroneously showed that Product Number 17902 was sold, which would have been illegal. However, Product Number 17904 was actually sold, and that sale would have been a legal sale. [Tr. 2395-97].

2. Erroneous Sale of Tableted SLC Product

144. The Respondent discovered five erroneous document entries in its system of approximately 350,000 pages of maintained entries. [Tr. 680]. Three

of the errors involved the transposing of product item numbers. [Tr. 680]. The transposed numbers resulted in the records indicating that the Respondent had sold and shipped SLC products into the States of Kentucky and North Carolina after it was illegal for that type of SLC product to be shipped. [Tr. 680-81, 1347-50].

145. Specifically, according to the Respondent's records, it sold tableted SLC product (Product Number 17550) to convenience stores in the states of Kentucky and North Carolina, after these two States had enacted legislation which only allowed pharmacies or pharmacists to sell tablet versions of SLC products. [Tr. 1449-51; Govt. Exh. 37, 65].

146. At the hearing, Mr. Merlau admitted that the Respondent's records were in error regarding the sales identified by the DEA. Specifically, Mr. Bledsoe credibly testified that product number 17550 had been discontinued and that the sales representative must have entered that number in the hand-held computer by mistake. [Tr. 1347-50]. That product had been discontinued by the Respondent over 12 months prior to the recording of those sales. [Tr. 2398-99].[13]

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[13] On cross examination, Mr. Bledsoe credibly testified, however, that he could not confirm that what he perceived was a recordkeeping error, was not in fact an actual product error, since he does not know at any given time what SLC products are in an individual sales representative's mini-warehouse, or on that person's delivery van. [Tr. 1404-06].

147. Mr. Merlau contacted representatives from the identified stores and confirmed that only gelcap forms of ephedrine and pseudoephedrine containing products had been sold. [Tr. 2292-94; Resp. Exh. 46]. In fact, gelcaps had actually been distributed. [Tr. 680].

148. After discovering this error, the DEA did not inform the Respondent of its discovery. Rather, the first time the Respondent became aware of the DEA's concerns was when it received the Order to Show Cause and Immediate Suspension Order. [Tr. 1416-17].

149. Around the end of 2006, the Respondent modified the hand-held computers used by the sales representatives to enter product codes. [Tr. 1404]. Mr. Bledsoe and Mr. Merlau credibly testified that the computer upgrades would prevent the erroneous entry of a product code for a discontinued product. [Tr. 1394-95, 2397-98].

3. Erroneous Sales of SLC Products to Convenience Stores Not Self-Certified

150. The DEA considers a company self-certified when the company files a self-certification application. [Tr. 1335-36]. The DEA has experienced a back log in compiling and placing self-certification information in the DEA's database. [Tr. 1338-39].

151. DI Barnhill obtained the Respondent's sales records, used the addresses of the Respondent's customers receiving SLC products from these records, and referenced the DEA's internal self-certification list to determine whether the Respondent's customers were self-certified, in compliance with the CMEA. [Tr. 1214-18; Govt. Exh. 39, 40]. DI Barnhill found that some of

the customers' addresses did not correspond with addresses for self-certified entities in the DEA's internal record of self-certifications. [Tr. 1216-17; Govt. Exh. 39, 40]. DI Barnhill concluded that a convenience store was not self-certified if she "did not see an address in that (DEA's) database that matched the Respondent's printout." [Tr. 1217-18; Govt. Exh. 39]. She therefore concluded that these stores were not self-certified. [Tr. 1218-19].[14]

152. According to the Respondent's records, DI Barnhill determined that, during the six-month audit period, the Respondent sold approximately 1.1 million dosage units to retail entities that were not self-certified. [Tr. 1218-19; Govt. Exh. 40].

153. Mr. Merlau checked the Respondent's customers' self-certification status by using the store

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[14] The record does not contain evidence of any additional DEA investigation into the self-certification status of the questioned convenience stores prior to reaching its conclusion that the stores were not self-certified.

number of the customer. When verified in this manner, the Respondent's records showed that all of the retail convenience stores identified by the DEA were self-certified. [Tr. 641-42, 677-79, 1329; Resp. Exh. 57 and 57A]. Thus, the Respondent did not sell SLC products to non-self-certified retail entities in violation of the CMEA.

154. Further, Mr. Bledsoe credibly testified that he assisted Respondent's new customers in obtaining self-certifications. [Tr. 1359-62; Resp. Exhs. 14, 44, 48].

F. *Respondent's Audit*

155. On July 9, 2007, as part of the administrative inspection, DI Barnhill participated in a physical inventory count of the 20 SLC products the DEA had chosen to audit, with the majority being ephedrine products. [Tr. 1162, 1164, 1522; Govt. Exh. 4]. The initial inventory was obtained by using the Respondent's records dated December 25, 2005. The closing inventory, which was a physical count taken by DEA investigators and the Respondent's employees on July 9, 2007, was used, and both counts were as of the close of business on their respective dates. [Tr. 1162-63; Govt. Exh. 4]. The inventory counts were certified by both DEA investigators and Respondent's representatives. Tr. 1163-64; Govt. Exh. 4; *see also* Tr. 1166-67; Govt. Exhs. 34, 35].

156. Mr. Polk and other Respondent's employees assisted the DEA in conducting the closing inventory count on July 9. [Tr. 1522-23].

157. In preparing the closing inventory, and with the agreement of the Respondent's personnel, the DEA personnel did not count all of the Respondent's product in the returns portion of the storage cage. [Tr. 1502]. These items consisted of out-of-date SLC products, broken blister packs, and single, loose pills, most of which were not in resalable condition. [Tr. 1503]. This return inventory had not been logged back into the Respondent's record system. [Tr. 1503].

158. The Respondent also provided the DEA with documents depicting sales of the 20 audited SLC products during the audit period. [Tr. 1167; Govt. Exh. 35].

159. The Respondent also provided the DEA with a list of the Respondent's purchases of the audited SLC products during the audit timeframe. [Tr. 1166; Govt. Exh. 34].

160. The inventory period was from December 25, 2006, through the close of business on July 9, 2007. [Govt. Exh. 4 at 1].

161. DI Barnhill prepared an audit computation chart, using the information provided by the Respondent and the final inventory count. [Tr. 1165, 1181-1182; Govt. Exh. 4 at 3]. The audit revealed that the Respondent sold more ephedrine product than it should have had in its inventory according to its own

documents. [Tr. 1185]. This results in overages. [Tr. 1184-85]. The Respondent had overages in 15 of the 20 audited ephedrine products. [Govt. Exh. 4 at 3]. These overages ranged between 576 dosage units to 50,496 dosage units. [Govt. Exh. 4 at 3]. The chart also revealed that the Respondent was unable to account for ephedrine product in two packaging types, one totaling a shortage of 27,924 dosage units, and the other totaling a shortage of 32,913. [Govt. Exh. 4].

162. The DEA also obtained summaries of purchase records from the Respondent's suppliers for four of the SLC products audited by DEA. [Tr. 1185-87, 1191-1195; Govt. Exh. 30-33]. As presented for the record in this proceeding, these documents did not include the actual invoices, however. These summaries did not balance with the purchase records provided to the DEA by the Respondent.[15] [*Id., see also* Tr. 1188-89; Govt. Exh. 69].

163. DI Barnhill then recalculated the audit results using the purchase quantities reflected in the records of the Respondent's suppliers for the audit time period. [Tr. 1186-87; Govt. Exh. 4]. Her computation chart reflected overages in all four products, ranging from 5,856 to 275,664 dosage units. [Tr. 1187-88; Govt. Exh. 4].

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[15] Although the DEA's audit chart includes data from BDI, neither BDI's summary of invoices nor the actual BDI invoices are a part of this record. [*See* Govt. Exh. 4, 30-33].

164. Mr. Polk reconstructed the documents from the audit period, and he noted that the DEA excluded three sets of documents. [Tr. 2039; Resp. Exh. 36]. Specifically, Mr. Polk testified that the DEA failed to take into account data for returns to vendors, data for items that had been removed to the expired or obsolete inventory area, and miscellaneous transfers or adjustments. [Tr. 2039; Resp. Exh. 36].

165. Mr. Polk credibly testified about discrepancies the Respondent found when attempting to recreate the numbers used by the Government in its computation chart. [Tr. 2034-37]. He was unable to reach the Government's overage calculations using the Respondent's records and the DEA's inventory count on July 9, 2007. [Tr. 2035-37]. Yet, Mr. Polk did note that, in calculating the shortages for Product Item No. 17902, the DEA had failed to account for a transaction of 28,800 units, when the Respondent had sent that product back to the original manufacturer because it was an obsolete item. [Tr. 2036-37; Resp. Exh. 36 at 5]. Mr. Polk credibly testified that he had given this return information to the DEA as part of their document request. This 28,800 unit return changes the shortage number for this SLC product from 27,924 to an overage of 876 dosage units. [*See* Tr. 2036-37].

166. Yet Mr. Polk's own document (1) shows a return of 57,600, (2) fails to show the dates of the returns, and (3) fails to show any underlying documentation demonstrating the actual transfer to BDI. [Resp. Exh. 36 at 5].

G. *Medicinal Uses for Ephedrine and Pseudoephedrine Products*

167. Dr. Pacin, an allergist and immunologist, credibly testified at the hearing concerning the legitimate medical uses for ephedrine products. He has practiced in this specialty for approximately 34 years. [Tr. 2409]. He primarily treats patients with chronic asthma and other respiratory conditions. [Tr. 2409-10]. Dr. Pacin was recognized as an expert witness in the areas of the treatment of asthma and upper respiratory infections. [Tr. 2415; *see also* Tr. 2409-15; Resp. Exh. 1 for his qualifications].

168. Dr. Pacin credibly described asthmatic symptoms as follows:

> Asthma usually presents in my office as a patient who is coughing, wheezing, complaining of shortness of breath on exertion, complaining of tightness in the chest. These are the symptoms that are brought on or that the patients bring to us. What is going on inside their body is mostly being affected by their bronchial tubes. They are having constriction of their bronchial tubes. There is swelling in the walls of the bronchial tubes and there is an excessive amount of mucus coursing through the bronchial tubes.

[Tr. 2415].

169. Approximately 20 million people in the United States, or about 10% of the population, suffer from asthma. [Tr. 2416-17]. Approximately 75% of

people who suffer with asthma also have allergies. [Tr. 2417].

170. From statistics from the American Academy of Allergy, Asthma, and Immunology, there are approximately 5,000 hospital emergency room visits due to asthma symptoms each day. Approximately 1,000 people are admitted to the hospital every day with asthma symptoms, and about 11 people die each day from an asthma condition. Approximately 5,000 deaths a year are attributed to asthma conditions. [Tr. 2418].

171. A patient may experience an asthma attack as quickly as minutes from the time the patient encounters the triggering element, up to days after such an event. [Tr. 2436-37]. Ephedrine is quite effective in easing the bronchial constriction produced during an asthma attack. [Tr. 2437]. However the combination ephedrine medication would not act as quickly as a rescue inhaler. If the asthma attack was life-threatening, Dr. Pacin acknowledged that such a patient would need to seek emergency room treatment. [Tr. 2458-61].

172. On average 40,000 adults and/or children miss work or school each day due to an asthma attack. [Tr. 2419].

173. The primary treatment goal for an asthmatic patient is to improve their quality of life so they may function in a normal way, like going to work or school, for example. [Tr. 2416].

174. Dr. Pacin credibly defined an asthma action plan as follows:

> An asthma action plan is something every asthmatic should have which if he has a doctor who is taking care of him discusses what they're going to do if their asthma bothers them, what type of medications they're going to use and what their plan is if they should start having asthma symptoms.

[Tr. 2419]. Yet, approximately 76% of uninsured asthmatic patients do not have an asthma action plan. [Tr. 2444, 2472].

175. Dr. Pacin reviews the action plan with his patients to determine what the patient will do to reduce the number of allergens in their environment. These allergens are triggering the patient's asthma attack. Dr. Pacin also discusses how the patient should organize their medications and other actions to take to respond to an asthma attack. [Tr. 2420].

176. Ephedrine is a bronchial dilator. [Tr. 2420]. Dr. Pacin credibly explained that ephedrine:

> relaxes the smooth muscle cells that surround the bronchial tubes, thus allowing the bronchial tubes to expand and open up and not be constricted and it's the constriction of those bronchial tubes that causes that patients to wheeze, to feel tight in the chest, to cough.

[Tr. 2420-21].

177. When Dr. Pacin was first treating asthmatic patients, ephedrine and combination ephedrine drugs were the primary drugs used to treat such conditions. [Tr. 2412].

178. Ephedrine has been used for centuries to treat asthma. [Tr. 2421]. Dr. Glade, after conducting an extensive review of scientific literature focused on the safety and efficacy of ephedrine, concluded that, "when consumed according to the labeling instructions, which set limits on the per dose amount to be consumed and the daily amount to be consumed, I found that ephedrine was safe and effective." [Tr. 2517; *see also* Resp. Exh. 3 at 3-8]. Specifically, the FDA considers ephedrine to be a safe and effective bronchodilator when taken in 12.5 mg to 25 mg every 4 hours, up to 150 mg in a 24 hour time frame. [Resp. Exh. 3 at 3]. Further, Dr. Glade writes that the scientific literature shows that patients with chronic asthma have responded to two weeks of daily doses of 11 mg three times a day, for a total of 33 mg a day, or 25 mg once daily, with the effect of significant bronchodilation. [Tr. 2536; Resp. Exh. 3 at 3].

179. Ephedrine is often combined with guaifenesin, which thins the mucous secretions to help the patient eliminate such secretions from the sinus areas or the bronchial tubes. [Tr. 2444]. All of the physicians in Dr. Pacin's group use guaifenesin to treat upper respiratory problems. [Tr. 2445].

180. Further, Dr. Glade conducted a survey of peer reviewed scientific journals, and he concluded

from that review that guaifenesin "was indeed a safe and effective expectorant that is potentially useful in the treatment of asthma." [Tr. 2516; *see also* Resp. Exh. 3 at 1-2]. He also concluded that there was "no evidence that guaifenesin interferes with or decreases the effectiveness of the bronchodilator, ephedrine." [Tr. 2538-42; Resp. Exh. 3 at 8].

181. Pseudoephedrine is used as a nasal decongestant, and it has been found that pseudoephedrine is not an effective bronchodilator. [Tr. 2537; Resp. Exh. 3 at 8].

182. Dr. Pacin advises his patients to use prescription medications as part of their treatment plan. [Tr. 2421]. There are two categories of medications asthma patients should use. First, there are "controller medications," which "control the symptoms and try to prevent the patient from . . . having (an) asthma attack," and there are bronchial dilator medications, which are "rescue medications." [Tr. 2422]. Both of these types of medications come in inhaler forms. [Tr. 2422]. The bronchial dilator medications also come in a pill form. [Tr. 2422-23].

183. Prescription inhalers are extremely expensive. Even with insurance, a patient may have a $50.00 to $75.00 co-pay for each inhaler. [Tr. 2423]. The over-the-counter asthma medications are considerably less expensive. [Tr. 2423]. So, lack of money is the primary barrier for patients to use inhalers. [Tr. 2426]. Patients often try to obtain sample inhalers

from their physician, or they purchase over-the-counter medications to ease the restriction in the bronchial area. [Tr. 2427].

184. Another barrier is that patients often have great difficulty using inhalers. [Tr. 2424]. Specifically, 89% of patients using inhalers do not use them correctly, and 50% to 79% of non-pulmonary physicians fail to explain correctly how to use an inhaler. [Tr. 2425; Govt. Exh. 64 at 235]. Patients also need to be frequently re-taught how to use inhalers because of the infrequency of use for many asthma patients. [Tr. 2425-26].

185. Patients without insurance usually fail to see physicians for asthma treatment. In the United States, approximately 18% of asthma patients do not have insurance. [Tr. 2442]. Approximately 36% of uninsured asthma patients do not have treating physicians for their asthma condition, thus they fail to have access to someone to guide them in the treatment of their asthma. [Tr. 2443]. Such patients then rely on over-the-counter medication to treat their symptoms. [Tr. 2433]. Such medications include combination ephedrine products as well as over-the-counter inhalers. [Tr. 2434]. Such patients do not have many medication options. [Tr. 2476-77].

186. Often sinusitis is a co-morbidity of asthma. Patients with asthma often also suffer from sinusitis, which will aggravate their asthma. [Tr. 2436, 2461]. Dr. Pacin often prescribes pseudoephedrine products in combination with guaifenesin to patients with

sinusitis, nasal allergy symptoms, and upper respiratory tract infections. [Tr. 2435, 2451-52].

187. In his report, Dr. Pacin noted that the need for ephedrine cannot be measured "in yearly increments and then dosed out on a monthly basis." [Resp. Exh. 1 at 7]. For the occurrence of asthma and upper respiratory infections "tend to have peaks and valleys," such as the start of the school year or during seasonal allergy times of the year. [Resp. Exh. 1 at 7].

188. Dr. Pacin credibly testified that, if one of his patients was traveling and did not have access to their prescription medications, he would recommend that patient use an ephedrine product to respond to an asthma attack. [Tr. 2438-39]. However, he also acknowledged that he does not usually recommend his patients take combination ephedrine products as part of their asthma action plan, because "(i)t's not the modern way to treat the patients." [Tr. 2468].

189. Dr. Pacin also observes that the mobility of the population oftentimes creates situations where asthma patients must rely on over-the-counter medications when they are out of contact with their physicians. [Resp. Exh. 1 at 7]. Specifically, Dr. Pacin notes that:

> (e)phedrine is a useful product especially for those patients who do not have the primary care physician or the specialist to fall back on. A patient may have an immediate need to prevent an emergency room visit or a chronic need just to go on with their regular lives

> dealing with a chronic respiratory problem such as an asthma attack or an exacerbation of their chronic bronchitis.

[Resp. Exh. 1 at 7]. In those instances, such patients may need to self-administer over-the-counter ephedrine-containing medications while they are out of contact with the family physician. Dr. Pacin concludes, on this point, that: "If OTC ephedrine-containing medications are not ubiquitous in the market and readily available, such as in convenience stores, there will likely be increased emergency room visits, hospital admissions and possibly worse." [Resp. Exh. 1 at 7].

190. Yet Dr. Pacin also acknowledged that two reliable sources of information from the National Institute of Health failed to mention ephedrine as a treatment option for asthma. [Tr. 2458, 2467; Govt. Exh. 93, 95; *but see* Govt. Exh. 64 at 229 (stating ephedrine is useful in treating mild forms of seasonal or chronic asthma)].

H. *Use of Ephedrine to Manufacture Methamphetamine*

191. Ephedrine SLC products may be used to manufacture methamphetamine. Specifically, Mr. Snyder wrote in his declaration:

> Most of the clandestine laboratories found in the United States are using tablets, either single entity or combination tablets. Many of the methamphetamine exhibits analyzed by DEA analytical laboratories detect the

> presence of antihistamines, indicating combination products were utilized in the reactions.

[Govt. Exh. 19 at 9].

192. Mr. Snyder also noted that gelcaps and liquid dosage forms of SLC products can be used to product [sic] illicit methamphetamine. [Govt. Exh. 19 at 9]; *see also* Resp. Exh. 22 at 2].

193. The street price for a gram of methamphetamine was between $20.00 and $50.00 per gram. [Tr. 2175, 2177, 2217].

194. Consistent with the experience of a prior law enforcement officer who became a criminal defense attorney in the Shenandoah Valley[16], the primary source of ephedrine products for the manufacture of illicit methamphetamine in this region is big-box stores where the products can be purchased at a discount price, and, to some extent, from a local grocery chain. [Tr. 2215-17]. When asked about convenience stores as the source for ephedrine products, the witness credibly testified:

> I have never dealt with a case where a convenience store has been used. And in my discussion with everyone else, convenience stores are not the primary source. The

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[16] I recognized this witness as an expert witness concerning street sources and prices of methamphetamine in the Shenandoah Valley. [Tr. 2215].

> discussion will – asking a couple of my clients who are meth users, they don't get their products from convenience stores.

[Tr. 2216, 2218-19].

195. Dr. Kupiec, a forensic toxicologist and pharmaceutical scientist, credibly explained how to extract ephedrine or pseudoephedrine from over-the-counter products to manufacture methamphetamine. [Tr. 2549-61; Resp. Exh. 55; *see also* Govt. Exh. 22 and Resp. Exh. 22]

196. Based on the skill of the "cook", the conversion of over-the-counter product to methamphetamine may yield between 0.3% to 30.7%. [Tr. 2568; Resp. Exh. 55 at 6]. Only using pure pseudoephedrine powder will produce a yield comparable to the range Mr. Snyder predicted, which was 50-70%. [Tr. 2568-69; Resp. Exh. 55 at 6]. Using a conservative conversion rate, Dr. Kupiec calculated a conversion rate of 32%, meaning that for every milligram of ephedrine extracted, approximately 0.32 milligrams of methamphetamine would be produced. [Tr. 2575]. Further, depending on the strength of the individual SLC product, a methamphetamine laboratory would need between 104 and 248 ephedrine pills to produce one gram of methamphetamine. [Tr. 2571-77; Resp. Exh. 55 at 12]. Using the Respondent's customer's range of retail prices for the Respondent's SLC products, it would cost a methamphetamine cook between $50.00 and $144 to produce 1 gram of methamphetamine. [Tr. 976, 995-96, 712, 718, 723,

789, 801-02, 853, 871-72; Govt. Exh. 77; Resp. Exh. 55 at 12].

I. *"Expected Sales" of SLC Products*[17]

1. General Background of Mr. Robbin

197. Based on the credentials of Mr. Robbin, which includes but is not limited to his extensive work in market research analysis over the course of 40 years and his work as a consultant for the Federal government and private sector entities, he was identified as an expert witness in these proceedings, specifically in the following areas: (1) Research of statistical data to include multivariate statistics through governmental data bases and business data bases in the private sector; (2) applied statistical analysis to include target marketing and market size and to draw statistical inferences from these types of information; and (3) population and economic census data and quantitative marketing research. [Tr. 219-224; Govt. Exh. 25].

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[17] This section is focused specifically on the central issue, namely the monthly expected sales value of SLC products. I do note that there was extensive testimony offered on other relevant areas and a complete synopsis of both Mr. Robbin's and Dr. Shepherd's testimony have been included in an Appendix to this decision.

2. Mr. Robbin's Methodology in Calculating The Monthly Expected Value of Ephedrine

198. In an analysis Mr. Robbin prepared for another DEA proceeding involving CBS Wholesalers ("CBS"), Mr. Robbin determined the monthly expected sales of ephedrine in convenience stores. [Tr. 223-24]. Mr. Robbin did not use a multivariate statistical approach in determining the monthly expected value of ephedrine, noting it was not necessary. [Tr. 291-92].

199. Mr. Robbin used various data sources, including the Economic Census, the National Association of Convenience Stores Trade Association ("NACS"), Mediamark Research Incorporated ("MRI"), and Information Resources Incorporated ("IRI"). [Tr. 226-27].[18]

200. In the Economic Census, nonprescription drugs are classified in the broad Health and Beauty Care category (Code 20160). [Tr. 301-02]. This category includes a panoply of health and beauty care products ranging from anti-itch ointment to lipstick. [Tr. 301]. However, a subcategory to the Health and

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[18] Mr. Robbin offered an extensive explanation of his methodological approach during his testimony. However, in the Rebuttal Declaration of Jonathan E. Robbin (Govt. Exh. 99), he provides a more step-by-step explanation of his methodology. Therefore, I am focusing on the latter explanation in this section; however, a more detailed summary of his testimony concerning his methodology is included in the Appendix section of this opinion.

Beauty Care exists and specifically represents only nonprescription drugs (Code 20162). [Tr. 302; *see* Govt. Exhibit 25B at 2]. Nonprescription drugs, as defined by the Census Bureau, include over-the-counter packaged medicines for various illnesses or symptoms, where a purchaser does not require a doctor's prescription. [Tr. 309]. An example is ephedrine guaifenesin. [Tr. 310].

201. In the NACS survey, the sale of nonprescription drugs is included in the Health and Beauty Care category; however, this category is further broken down into a Health and Beauty Care – Cough and Cold Remedies subcategory. [Tr. 341-42; *see* Govt. Exhibit 25B at 2]. Ephedrine guaifenesin would fall into this subcategory. [Tr. 342]. Other products in this subcategory would include, for example, cough syrups, allergy and sinus remedies, and Tylenol. [Tr. 343].

202. The following was Mr. Robbin's methodology in arriving at the monthly expected sales figure of $14.39:

(i) Mr. Robbin first determined the average monthly sales per store of cough and cold products for 2006. [Govt. Exh. 99 at 2]. The Census for 2002 indicated that 50 percent of all convenience stores reported carrying Health and Beauty Care (HBC) products (Code 20160) and 31.5 percent reported carrying nonprescription drug medicines (Code 20162). [Govt. Exh. 99 at 7, 11]. These figures were then applied to the information located in the NACS

survey, which lists revenue by product category. [Govt. Exh. 99 at 7]. Mr. Robbin used the 2007 NACS survey but adjusted the figures to reflect the 2002 Census trends.[19] [Govt. Exh. 99 at 8].

(ii) The next step in Mr. Robbin's methodology was to calculate the monthly expected sales of ephedrine product per convenience store for 2006. [Govt. Exh. 99 at 8]. First, Mr. Robbin determined that the estimated average monthly sales per store for cough and cold products was 8.36 percent, derived from a tabulation of MRI data which showed the use of asthma remedy products in convenience stores.[20] [Govt. Exh. 99 at 8, 12]. Mr. Robbin was able to further adjust this figure using MRI data that listed

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[19] Mr. Robbin's explanation is more descriptive than numerically specific; however, while he notes the tables he used and generally narrates his approach, he does not provide specific calculations to aid the trier of fact in showing how he used specific numbers. I further note that Mr. Robbin's declaration (Government Exhibit 25) does not provide this information, either.

[20] Mr. Robbin provides a table listing the data he references; however, it is not clear whether these calculations were done by MRI or if he calculated the figures using MRI data and prepared the table himself. Given his statement that the 8.36 percent figure "was derived from a tabulation of MRI data showing asthma remedy usage by retail channel (in this case, convenience stores) as shown in Table 1, I conclude that Mr. Robbin calculated the figures using MRI data and prepared the table. However, it is not clear what calculations Mr. Robbin performed; he does not specifically lay out his methodology here with facts for each step taken, other than providing a narrative and including the table with the ultimate figures he devised.

the form of asthma remedy (e.g. powers, tablet, liquid), which yielded an average monthly sales estimate of $14.78.[21] [Govt. Exh. 99 at 8, 11].

(iii) Mr. Robbin then referenced the "Redbook," which lays out average wholesale prices for the top branded ephedrine products – Bronkaid and Primatene – which are $3.45 and $4.95 respectively, and then using the gross margin figure (noted in NACS survey for 2007), calculated the average retail price to be $5.91 and $8.48. [Govt. Exh. 99 at 8, 11]. Mr. Robbin then took the average of these two products ($7.19) and then multiplied by two to get a final monthly sales average of $14.39.[22] [Govt. Exh. 99 at 8, 11].

3. General Background of Dr. Shepherd

203. Based on the credentials of Dr. Shepherd, she was found to be an expert witness in these proceedings in the areas of statistics and applied statistics. [Tr. 1635]. Dr. Shepherd has a Ph.D. in Economics, with a concentration in applied statistics (econometrics) and law and economics, from Emory

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[21] It is not clear how Mr. Robbin arrived at the $14.78 figure because the data which he references in his narrative is not supplied, and he does not provide a detailed step-by-step approach to his calculations.

[22] Mr. Robbin explains that he multiplied the average retail sales figure by two, a "reality check," to be in line with the expected ephedrine tablet average monthly sales per store of $14.78. [Govt. Exh. 9].

University. [Tr. 1597; Resp. Exhibit 58]. Dr. Shepherd is currently a Professor of Law at Emory University where she teaches various economics and statistic courses, and she has a total of 19 publications, 15 of which are statistical papers, with 14 of these papers using Census Bureau data. [Tr. 1597-98, 1864; Resp. Exhibit 58 at 1-2].

204. Dr. Shepherd was offered as an expert witness to refute Mr. Robbin's methodology and to highlight the deficiencies in Mr. Robbin's calculations and his monthly expected sales value of $14.39. [Tr. 116-17].

205. Dr. Shepherd was not offered as a witness to offer her opinion as to the proper monthly expected sales value of ephedrine products nor was she offered as a witness to testify concerning her March 12, 2008 report she prepared for Novelty. [Tr. 1631-32].

206. Had Dr. Shepherd prepared a report concerning the accurate monthly sales estimate of ephedrine products per convenience store, she would have performed a multivariate statistical analysis, controlling for different factors. [Tr. 1621, 1630-31].

4. Problems in Mr. Robbin's Analysis

207. Dr. Shepherd highlighted the problems with Mr. Robbin's methodology both in her testimony at the hearing and in her surrebuttal declaration (Respondent Exhibit 59).

208. Based on Mr. Robbin's testimony and the information provided in his declaration, Dr. Shepherd deduced that the formula he used was the following:

$$\frac{\$292{,}000{,}000}{140{,}000} * .08 * \frac{1}{12}$$

The figure $292,000,000 represents the total amount of sales of cough and cold products for the entire convenience store industry; figure 140,000 represents the total amount of convenience stores in the country; 0.08 represents the percentage of sales of cough and cold products that are ephedrine-based products; and then multiplying by 1/12 yields a monthly average.[23] [*See* ALJ Exh. 15 at 1; Resp. Exh. 59 at 8].

209. Based on Mr. Robbin's rebuttal declaration (Government Exhibit 99), Dr. Shepherd notes the following formula was used to come to the $14.39

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[23] Dr. Shepherd testified extensively about the problems with the figures Mr. Robbin used; however, given that Mr. Robbin stated that she did not correctly showcase the formula he used during her testimony (as he states in his rebuttal declaration (Govt. Exh. 99)); I will focus on the purported formula Mr. Robbin used as highlighted in Dr. Shepherd's surrebuttal declaration (Resp. Exh. 59) to maintain clarity in the opinion. However, Dr. Shepherd's testimony at the hearing, where she showcases step-by-step the problems with Mr. Robbin's approach, is provided in the Appendix. Furthermore, I note that regardless of either of the calculations Dr. Shepherd imputes to Mr. Robbin's analysis, the underlying problems are strikingly similar and Dr. Shepherd's demonstration of the problems in Mr. Robbin's analysis is consistent.

expected monthly sales value of ephedrine products per convenience store:

$$\frac{\$292{,}000{,}000}{71{,}565} * .08 * \frac{1}{12} * .52$$

The figure $292,000,000 represents the total amount of sales of cough and cold products for the entire convenience store industry; figure 71,565 represents the total amount of convenience stores in the country carrying any product within the Health and Beauty Care line (Code 20160), as noted in the Census; 0.08 represents the percentage of sales of cough and cold products that are ephedrine-based products; then multiplying by 1/12 yields a monthly average; and figure 0.52 represents the percentage of total number of users that ingest tablets instead of inhalers. [Resp. Exh. 59 at 8].

210. By using the 71,565[24] figure in the denominator, Mr. Robbin is assuming that all convenience stores which carry the Health and Beauty product line also carry ephedrine products, which is not the case. [Resp. Exh. 59 at 10]. The tables Mr. Robbin uses shows that out of the total 71,565 convenience stores that carry the Health and Beauty Care product line, only 45,077 of the stores carry nonprescription drugs. By using the larger number of stores in the denominator, Mr. Robbin is forcing a lower expected sales value. [Resp. Exh. 59 at

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[24] This figure is noted in the tables Mr. Robbin provides in his rebuttal declaration. [*See* Govt. Exh. 99 at 11].

10]. Additionally, Mr. Robbin is not taking into account that certain states (12) either severely restrict or prohibit the sale of ephedrine-based products, which is a relevant factor. [Tr. 1669, 1918; Resp. Exh. 59 at 10]. Taking this factor into account, the number of stores that could carry ephedrine products logically goes down, and so the legitimate number that can be used in the denominator goes down. [Tr. 1670, 1920; Resp. Exh. 59 at 10]. This, in turn, results in the monthly expected sales number rising.[25] [Resp. Exh. 59 at 11].

Mr. Robbin does not provide a detailed breakdown of how he came to the 8 percent figure, other than providing a narrative of his approach and including a tabulation of MRI data. [*See* Govt. Exh. 99 at 8]. Additionally, there is no evidence that MRI data takes into account ephedrine-based products in its survey. [*See* Rep. Exh. 59 at 11, Attachment C at 11-12]. Rather, Mr. Robbin imputes data for his calculation from MRI relating generally to non-prescription drug purchases, which does not provide any specific information on ephedrine or its relation

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[25] Dr. Shepherd follows this same analysis during her testimony to show that by not taking into account that (1) not all stores carry nonprescription drugs, and (2) certain states have stringent laws, the total number of stores used in the denominator is inflated. [Tr. 1669-70, 1918, 1920; *see* ALJ Exh. 15 at 3].

to convenience store purchases.[26] [Resp. Exh. 59 at 11, Attachment C; *see* Govt. Exh. 99 at 8, 12].

212. With regards to the 52 percent figure, while this figure is listed in one of the tables affixed to Mr. Robbin's rebuttal declaration that explains his methodology, there is no clear evidence to show how Mr. Robbin arrived at this percentage figure to represent individuals who ingest ephedrine tablets.[27]

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[26] Dr. Shepherd also criticizes Mr. Robbin's use of the eight percent figure during her testimony at the hearing, noting that it is not proper to impute a percentage that represents the entire retail industry to convenience stores, without taking into account the variation that exists between large retail entities and convenience store entities, specifically store size. [Tr. 1674-76].

To highlight the importance of using a figure that is reflective of the convenience store sector, Dr. Shepherd, in both her testimony and her surrebuttal declaration, used a 60 percent figure she received from Novelty, which Novelty stated represented the percentage of its customers' sales of cough and cold products directly attributable to ephedrine tablets. [Tr. 1676-77, 1907-08; ALJ Exhibit 15 at 1; Resp. Exh. 59 at 12, 13]. Using the 60 percent figure instead of the eight percent figure Mr. Robbin uses, the monthly expected sales per store of ephedrine tablets rises. [Tr. 1676-77; ALJ Exh. 15 at 1; Resp. Exh. 59 at 11-12]. While this figure is not meant to be an accurate percentage of the convenience store industry as a whole, inserting it into the equation highlights the importance of ensuring the degree of accuracy of the figure used.

[27] A 52.4 percent figure is listed in the Table with the heading, "Table 1, MRI 2004 Doublebase Tabulation, Extrapolated to 2006;" however, it is not clear if this is the same figure Mr. Robbin attributes to the percentage of ephedrine users who use tablets instead of inhalers. If so, Mr. Robbin does not show how he arrived at this conclusion in his narrative of his

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[*See* Govt. Exh. 99 at 11]. Mr. Robbin notes that this is also tabulated from the MRI survey; however, while his table reflects a 52.4 percent figure, there are no calculations or formulas involved to direct the trier of fact. [*See* Govt. Exh. 99 at 8, 11]. Thus, the trier of fact can not [sic] evaluate the accuracy of this 52.4 percent figure.

213. With regards to the $292 million figure denoting the total amount of sales of cough and cold products, Mr. Robbin does not take into account that all ephedrine-based products might not have been properly reported as cough and cold products by convenience stores responding to the surveys. [Tr. 1682-83, 1886]. Given the surveys that are being used in Mr. Robbin's analysis rely on self-reporting, there are likely to be variables in terms of how retail entities report their sales.[28] [Tr. 1683, 1886].

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methodology and it is not clear in looking at the tables provided by Mr. Robbin how he legitimately arrives at this figure. [*See* Govt. Exh. 99 at 11, 12]. He does not include the underlying MRI data to support the 52 percent figure he uses. Furthermore, given that the MRI information does not discuss ephedrine, it is not clear how Mr. Robbin imputes MRI information about cough and cold remedies specifically to ephedrine. [*See* Resp. Exh. 12].

[28] I note that Dr. Shepherd discussed reporting errors vis-à-vis Novelty, who told her that at least two of its largest customers report their sales of ephedrine under "general merchandise" rather than under the "cough and cold" category. [Tr. 1683, 1886]. While Novelty has a clear interest in the proceedings at hand, Dr. Shepherd's testimony at the hearing and her surrebuttal declaration further underscore the importance of taking into account varying factors within the

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5. Importance of Multivariate Statistics

214. In statistical analysis, multivariate statistics is a form of analysis that takes into account more than one variable to make a prediction or classification of an event or objects. [Tr. 176, 291]. Using multiple variables enables a more accurate prediction and stronger outcome and assists in ensuring there are no misleading conclusions. [Tr. 176, 291-92]. Multivariate statistics, when properly controlled, may explain up to 80 percent of the variation of the observable fact being measured. [Tr. 177].

215. By taking into account different variables at play when predicting a monthly average sales figure, a more precise outcome is achieved. [Tr. 1686-90].

216. Mr. Robbin did not account for outside variables in his calculation of the monthly expected sales of ephedrine per convenience store because, in his opinion, such variables would not have affected the expected sales value enough to have made a difference. [Govt. Exh. 99 at 5]. Applying this to Novelty, Mr. Robbins testified that, because Novelty's sales were 50 times over the expected mean, the stark

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analysis. Given entities are likely to misreport, then the total sales figure of cough and cold products would need to be enlarged, thereby affecting the outcome of the calculation. This variable needs to be taken into account in the analytical methodology used to reach this expected sales figure. [Tr. 1684, 1874; ALJ Exhibit 15 at 1; Resp. Exh. 59 at 13].

deviation essential "drowned out" any conceivable variation among stores in the general retail industry.[29] [Govt. Exh. 99 at 6].

217. Mr. Robbin did not use a multivariate approach in his methodology because, in his opinion, it is not needed when simply comparing the observed values to the expected value, and noting the variance between these values in order to determine whether the observed values occurred by chance or are very different from the expected value.[30] [Tr. 291-92].

218. Dr. Shepherd credibly testified that the inherent problem in coming up with one cumulative

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[29] I note that Mr. Robbin is using the monthly expected value that he computed – $14.39 – in his analysis of Novelty sales to reach his "50 times" conclusion, however. Additionally, while Mr. Robbin asserts that outside variables are "drowned out" by the large variance of Novelty's actual sales from the expected value, it is not clear to me that taking these factors into account in the approach from the front end would not alter the outcome. Based on Mr. Robbin's explanation, it seems that he is approaching the issue of using outside variables at the tail end of the analysis, while Dr. Shepherd asserts that outside variables need to be taken into account from the beginning in the calculation.

[30] I note that a large deviation outside of what is normally expected for ephedrine sales would indicate the diversion of ephedrine, according to DEA. However, Dr. Shepherd credibly testified that finding an observed value statistically different than the expected value is not outright indicative of illegitimate sales; there could be legitimate reasons to explain the difference, but one would need to rely upon additional information to explain it, information the Government did not pursue in its investigation. [Tr. 1700, 1703].

number to represent all stores is that the stores that comprise the industry vary as well; therefore, a multivariate approach is necessary to account for these differences. [Tr. 1686]. Factors such as store hours, store location, store size, advertising expenditures, and management practices, should be taken into account. [Tr. 1686-88].

219. Furthermore, focusing in on ephedrine products alone, Dr. Shepherd credibly testified that it is important to account for seasonal and environmental variables, noting that asthma-related conditions are more prominent at certain times of year in certain regions of the country.[31] [Tr. 1688-89; *see also* FOF 187 and Dr. Pacin's analysis of these same asthma-related factors].

J. *Respondent's Efforts to Comply*

220. The Respondent provided to its customers lockable, Lucite cabinets for the secured storage, display, and sale of SLU products. [Tr. 660]. The cabinets contain reminder stickers, reminding the store clerks to use the logbooks and to limit the sale

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[31] I note that Dr. Shepherd is not a medical doctor. However, I find that her testimony on the importance of taking into account seasonal and environmental factors when determining ephedrine sales is directly applicable to her testimony on ensuring that various variables are accounted for in statistical methodology. Further, her notation of asthma-related variables is supported by medical testimony given in this proceeding. [FOF 187].

of such products. [Tr. 660-61; 781]. The Respondent's sales representatives stock the cabinet and ensure the display cabinet is maintained properly. [Tr. 662].

221. When the CMEA made it illegal to sell SLC products packaged in a certain manner, the Respondent not only ceased selling those products, but also removed the products from its customers' shelves and appropriately disposed of them. [Tr. 1349-50].

222. Also after the CMEA, the Respondent supplied the logbooks for its customers' use. [Tr. 144].

223. Mr. Bledsoe credibly testified that, after the CMEA came into effect, the Respondent developed software:

> that would prevent a sales person from selling the wrong item number into a particular store located inside a state (that prohibited the sale of that product). The handheld computer that the sales person carries knows what state that store is in, and if, for example, the sales person is in the State of Kentucky, that only allows ephedrine to be sold in a 25 milligram gel capsule form, then it would prevent that sales person from entering an item number that was of a tablet form, or would prevent that sales person from entering an item that was in a pseudoephedrine.

[Tr. 1400; *see also* Tr. 1433, 1436-37].

224. The product codes can be manually entered into the handheld computer, or they can be scanned into the computer using the product SKU bar. [Tr. 1410].

225. This software came into effect between the end of 2006 and May of 2007. [Tr. 1410]. Yet, Mr. Bledsoe credibly testified about recordkeeping errors that occurred after this time, regarding the sale of a specific SLC product into a state that prevented the handling of such a product. Mr. Bledsoe explained that, when the software was developed, he had failed to block the discontinued product numbers from being entered in the handheld computers. The product in question involved in the recordkeeping errors was such a discontinued product. [Tr. 1410].

226. At the hearing, representatives of the Respondent confirmed that the Respondent will accept any conditions on its registration that the Administrative Law Judge believes necessary to reduce the risk of diversion. [Tr. 653-58, 662-63].

K. *Impact of the Suspension Order Upon the Respondent's Business*

227. Since the DEA served the Immediate Suspension Order in January of 2008, the Respondent has lost 15 to 20 customers, to include a large, chain store company. [Tr. 2249, 2257-58]. In revenue, the Respondent has lost approximately 1.6 to 1.7 million dollars as a result of this loss of business. [Tr.

2249-50]. This represents a loss of approximately 15% of the Respondent's gross revenue per year. [Tr. 558].

228. Mr. Merlau estimates that between 25 and 50 employees will need to be fired. [Tr. 2250].

229. Even prior to the suspension order, however, the Respondent's customer base for SLC products was shrinking due to the enactment of State laws and the CMEA. Some convenience stores chose to no longer sell SLC products due to the enhanced regulatory requirements. [Tr. 2364-65].

230. The Respondent's customers now purchase SLC products from other distributors, who are providing them with 25 mg strength ephedrine products rather than the 12.5 mg products the Respondent usually sold. [Tr. 2252]. The packaging provided by the new distributors is primarily 6-count and 24-count SLC product. [Tr. 2254].

L. *Execution of the Administrative Inspection Warrant*

231. On July 9, 2007, five DEA personnel, DI Meador, DI Kuzma, DI Barnhill, SA Carroll Harris, and Attorney Brian Bayly, initiated an inspection of the Respondent, using an administrative inspection warrant. [Tr. 1539, 2009, 2223]. Three of the personnel, DI Barnhill, DI Meador, and Attorney Bayly, were from DEA Headquarters in Washington, D.C., and DI Kuzma and SA Harris were from the DEA's Indianapolis office. [Tr. 1539, 2009]. Mr. Bayly

was only present on Monday and Tuesday of the first inspection week. [Tr. 2117].

232. At the time of the inspection, the Respondent had a legal case pending against the DEA in the Federal District Court for the District of Columbia. [Tr. 2006, 2224]. As part of that case, the Respondent had asserted that DI Meador had made a false statement to obtain the administrative inspection warrant he was now assisting in executing at the Respondent's location. [Tr. 2006-07]. DI Meador remained part of the team for three days, and on the fourth and fifth days of the warrant execution, DI Meador was not present. [Tr. 2007]. His absence helped to diffuse the tension between the Respondent's personnel and the DEA personnel. [Tr. 2105-06].

233. On the first day of the inspection, DEA personnel handed Mr. Polk the inspection warrant. [Tr. 2009]. The DEA investigators followed Mr. Polk to the warehouse, where they were given access to the caged area where the Respondent kept its SLC products. [Tr. 2009-10].

234. One area in the cage is a "rework" area where returned or damaged SLC product is received and further processed by the Respondent's personnel. On the second day of the inspection, DI Barnhill and others were in that area participating in taking a count of the SLC products. Mr. Polk heard DI Barnhill, upon finding an empty bottle, say something like

"meth heads must have used this and taken it back to the store for credit." [Tr. 2010].

235. Multiple times during the inspection, the Respondent would produce requested documents, and the DEA representatives would ask that additional "fields" be added to the computer-generated report, requiring the production of another set of documents, all consisting of hundreds of pages. [Tr. 2025-29, 2032-33]. These changing requirements, and the time constraints the DEA placed upon the Respondent for the production of additional documents, were burdensome. [Tr. 2029-31]. The Respondent had the data requested, but the time constraints for production were unrealistic, given the volume of documents to be produced. [Tr. 2031].[32]

236. However, one of the documents provided to the DEA by the Respondent during the inspection was a document that showed sales transactions. [Tr. 2079-80; Govt. Exh. 35]. Yet, without access to the Respondent's codes, the DEA representatives could not tell the following by looking at this document: (1) The ship to address; (2) the name of the individual to whom these SLC products were shipped; or (3) the identity of the items shipped. [Tr. 2079-81]. The additional documents requested by the DEA were

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[32] Later Mr. Polk learned that the DEA was operating under time constraints established by the Judge who issued the inspection warrant. [Tr. 2086].

needed to understand the coded sales transactions document. [Tr. 2080-81, 2095-98].

237. On the third day of the inspection, Mr. Polk met with DI Kuzma, DI Barnhill, and DI Meador. DI Barnhill advised Mr. Polk that she believed the documents provided had been "scrubbed," and that such conduct constituted impeding a federal investigation, for which he could be arrested and charged. [Tr. 1541, 2233-34]. DI Barnhill showed Mr. Polk a provision of the Code of Federal Regulations at that time. [Tr. 2115].

238. Mr. Polk did not know if any of the DEA personnel were armed or not. [Tr. 2113-15]. None of the DEA's personnel displayed handcuffs to him. [Tr. 2116]. Mr. Polk credibly testified that he did not believe that there was a basis to arrest him. [Tr. 2115]. Mr. Bayly was not present during this exchange. [Tr. 2119-2120]. Also, Mr. Merlau did not believe that he saw DEA badges, weapons, or handcuffs on the DEA personnel conducting the Respondent's inspection. [Tr. 2382-84, 2386-87].

239. DI Barnhill then requested 12,000 additional pages of documents, and she gave Mr. Polk three hours to produce them. [Tr. 1541-42]. Although physically impossible to accomplish, Mr. Polk believed that he would be arrested if he did not meet the DEA's deadline. [Tr. 1542-43, 2231-32].

240. Mr. Polk had the Respondent's information technology department develop a program that would transfer the 12,000 pages of data into a computer file

so that the data could be placed on a compact disk. The disk was then given to the DEA. [Tr. 1544-45].

241. Ultimately, the Respondent provided the DEA will all of the information it requested. [Tr. 2273-74].

242. Later that day, upon advice of counsel, the Respondent's personnel attempted to record interactions with the DEA's personnel. [Tr. 2378-79]. Specifically, after Mr. Polk perceived that the DEA representatives were threatening to arrest him, he worked with the Respondent's representatives to set up a video camera. At the hearing he specifically testified:

> I wanted to have some proof or documentation that what was happening was exactly what was ultimately going to come out about what happened that day was truthful. I felt the best way to do that would be to document that through some form of media.

[Tr. 2011].

243. While the DEA representatives were at lunch, the Respondent's representatives placed a small video camera in the conference room, in plain sight, and plugged it in. DEA personnel had not consented to being videotaped. [Tr. 2092-93, 2224-26]. The conference room was allocated as the working location for DEA personnel during the inspection, and it also served as the meeting room when the Respondent's personnel met with the DEA personnel. [Tr. 2092].

244. However, none of the Respondent's personnel were interrogated in this room. [Tr. 2109]. The Respondent did not maintain any SLC products or records in the conference room. Rather, the DEA personnel used the conference room to review materials provided by the Respondent's personnel during the course of the inspection. [Tr. 2093-95].

245. After the DEA representatives returned from lunch, they unplugged the camera and removed it from the room. [Tr. 2013, 2227]. The DEA's representatives objected and told the Respondent's representatives that they did not want the camera in the room. [Tr. 2014, 2020, 2373].

246. Later that afternoon, while DEA representatives were present, Mr. Merlau attempted to replace the camera in the conference room. Again, the DEA personnel did not consent to being videotaped. [Tr. 2108]. DI Meador grabbed the camera, yanked the plug from the wall, and took the camera back out into the hallway. [Tr. 2016-18, 2227, 2388-90, 2392-93]. Mr. Merlau objected to DI Meador's actions and told the DEA personnel that, upon advice of counsel, they believed they were entitled to videotape the DEA's actions during the inspection of the Respondent. In response, DI Meador stated that the Respondent's personnel were not going to be allowed to videotape the DEA's actions. [Tr. 2227-29].

247. The record contains no information that, between the first time the video camera was placed in the conference room and the second time that the

camera was removed from the conference room, the DEA and the Respondent's personnel conducted any meetings about the ongoing inspection. [Tr. 2370-72].

248. Subsequently, the Respondent's representatives attempted to audio record the proceedings in the conference room by placing a tape recorder on the end of the conference room table and depressing the record button. [Tr. 2020-21, 2228]. Mr. Merlau reported that the DEA representatives objected to the presence of the audio recorder and turned it off. [Tr. 2022; *see also* 2108]. Later that day, Mr. Polk returned to the conference room and found the recorder on the table with the batteries removed, the tape removed, and the battery cover removed from the recorder. [Tr. 2021-22].

249. Similarly, the record contains no information that, between the second time the video camera was removed from the conference room and the time when the audio recorder was removed from the conference room, the DEA and the Respondent's personnel conducted any meetings about the ongoing inspection. [Tr. 2373-75]. After the audio recorder was removed from the conference room, Mr. Polk had a meeting with DEA personnel. [Tr. 2376-78].

250. Regarding interaction between the Respondent's personnel and the DEA's personnel, Mr. Polk credibly testified at the hearing about his perceptions:

> Not until we had made contact with you, sir, (Mr. Barber) did we feel like we had an

> opportunity to have a dialogue in a manner that would not produce an excessive or an abusive action by a DEA investigator.

[Tr. 2109]. After counsel for the Respondent and Mr. Barber for the DEA conversed, the situation settled down. [Tr. 1543, 2023-24].

251. Further, after conversations occurred between DEA's counsel and the Respondent's counsel on Thursday of the inspection week, Mr. Polk believed recording devices were no longer needed. The Respondent's personnel did not attempt to place recording devices in the conference room after the conversation between the attorneys. [Tr. 2113].

252. Mr. Merlau credibly testified that none of the Respondent's personnel impeded the execution of the inspection warrant. Further, he also credibly stated that he did not believe that the DEA ever had a basis for arresting Mr. Polk. [Tr. 2365, 2384-85].

IV. CONCLUSIONS OF LAW AND DISCUSSION

A. Positions of the Parties

1. Government's Position

a. Generally

The Government summarizes its case against Novelty noting the following: (1) Novelty continued to sell large amounts of ephedrine products to its customers and the high level of sales cannot be explained by legitimate retail demand; (2) Novelty

failed to maintain effective controls against diversion of ephedrine by selling the product in large quantities that cannot be explained by legitimate retail demand; (3) Novelty distributed pseudoephedrine and ephedrine in an unlawful manner because it utilized over 150 public storage facilities in its distribution plan, none of which were registered with DEA; and (4) Novelty's recordkeeping requirements were not in compliance with both Federal and state law. [Govt. Brief at 2].

b. Novelty's Storage Facilities were not registered with DEA

The Government asserts that Novelty only has one registered location with DEA, which is its main warehouse location at its headquarters in Greenfield, Indiana. [Govt. Brief at 4]. However, Novelty used public storage units (approximately 150-180 units), in addition to its registered location, to store its products, including Scheduled Listed Chemical (SLC) products, from a few hours up to a few days, before its route sales professionals picked up the items to deliver to Novelty's customers. [Govt. Brief at 4, 7]. The SLC products that were stored in the public storage units were not shipped back to the registered location prior to being delivered to Novelty's customers. [Govt. Brief at 4]. Additionally, the public storage units did not have separate cages or other security mechanisms in which to store the SLC products. [Govt. Brief at 5]. When Novelty was notified by letter from the DEA that its practice in using unregistered public storage units was against

DEA policy, Novelty did not deviate from this practice. [Govt. Brief at 5].

The Government argues that Novelty was in direct violation of 21 U.S.C. § 822 (e) by not separately registering each individual facility in which it stored SLC products. [Govt. Brief at 5-6]. Additionally, Novelty's practice of distributing SLC products from the storage units to its customers did not fit within the exception of the registration requirement pursuant to 21 C.F.R. § 1309.23(b)(1) because none of the SLC products were first shipped back to the registered location. [Govt. Brief at 6]. While Novelty's representatives stated that the SLC products were not being "stored" in the public storage units, the Government stressed that the definition of "store" is clear and that Novelty's position on the issue is not credible. Given Novelty's continued violation of 21 U.S.C. §§ 823(e) and 843(a)(9), there is a strong basis to revoke Novelty's registration. [Govt. Brief at 8].

c. By Distributing Large Quantities of Ephedrine to Convenience Stores, Novelty Failed to Maintain Effective Controls Against Diversion

Approximately 90 percent of Novelty's sales of SLC products are made up of ephedrine/guaifenesin combination products. [Govt. Brief at 8]. While the Food and Drug Administration (FDA) used to approve

ephedrine/guaifenesin combination products as a treatment for bronchial asthma, the FDA no longer considers this an effective form of treatment for those suffering from asthma and who seek relief from over-the-counter drugs. [Govt. Brief at 9]. This fact highlights that there is no legitimate demand that would explain the large quantities of ephedrine that Novelty distributes to its customers. [Govt. Brief at 23].

The Government further highlights the illicit use of ephedrine, which can be used to produce methamphetamine. [Govt. Brief at 9]. The Government supports this contention by highlighting the declaration of Mr. Snyder, wherein Mr. Snyder notes that gel-caps and liquid forms of ephedrine and pseudoephedrine, as well as combination products, can be used to produce illicit methamphetamine. [Govt. Brief at 10]. Additionally, the Government focuses on the testimony of various DEA Special Agents who assert that (1) convenience stores, rather than large retailers, are where individuals producing methamphetamine prefer to purchase the necessary SLC products and they will go from store to store and purchase two packages at each store, (2) combination ephedrine products have been found at methamphetamine laboratories, (3) gel-caps, although not the preferred form of ephedrine, can be used to produce methamphetamine, (4) gel caps were discovered and have been used as precursors in the nephedrine/guaifenesin combination products as a treatment for bronchial asthma, the FDA no longer considers this an effective form of treatment for those

production of methamphetamine in Tennessee, Georgia, and Alabama, and (5) local drug task forces are seeing "gray market" ephedrine, which is not marketed at large retailers, being diverted to produce methamphetamine. [Govt. Brief at 10-13].

The Government highlights Diversion Investigator Kuzma's testimony that ephedrine products distributed by Novelty have been found in an illicit methamphetamine laboratory in Connecticut in 2002. [Govt. Brief at 13]. Specifically, DEA was able to trace the product to one of Novelty's suppliers, DMD, who confirmed that the products in question were part of a lot that was supplied to Novelty. [Govt. Brief at 13]. Novelty was informed of the issue and confirmed where the products were sold. [Govt. Brief at 14].

Supporting its contention that Novelty sold a large quantity of ephedrine products to its customers, the Government emphasizes the high level of sales of SLC products to some of Novelty's customers, including Roadrunner Market and Circle K stores, which are far above the expected retail sales of $50 per month and above the monthly expected value calculated by Mr. Robbin of $14.39 per month. [Govt. Brief at 15-16]. To further emphasize the large quantities of ephedrine that Novelty was selling to its customers and to emphasize the lack of legitimate demand for such products, DEA Diversion Investigators visited retail pharmacies located near some of Novelty's customers' stores that had large sales of ephedrine SLC products. [Govt. Brief at 22]. The investigators found a low demand for ephedrine SLC

products, little shelf space for such products, and safer drug alternatives available to consumers in the pharmacies. [Govt. Brief at 22-23].

Additionally, looking at the recordkeeping logbooks collected by DEA of some of Novelty's customers located in Indiana, New York, and Pennsylvania, there are multiple repeat purchasers, which is indicative of the diversion of ephedrine. [Govt. Brief at 17-21]. Some of these repeat purchasers made purchases on multiple consecutive days and made several purchases within the same day. [Govt. Brief at 19].

Further highlighting Novelty's excessive sales, the Government noted that Dr. Shepherd's Z-score analysis revealed the distribution by Novelty of more than $1000 worth of SLC products (retail value) on monthly basis to 561 of Novelty's customers in the 12 weeks prior to DEA suspending its registration in January 2008. [Govt. Brief at 17]. During this same period, 1,470 of Novelty's customers purchased more than $500 worth of SLC products on a monthly basis, and 2,870 stores purchased more than $150 worth of SLC products on a monthly basis. [Govt. Brief at 17].

In light of all of the above, the Government states that the high level of SLC products that Novelty distributes to its customers cannot be explained by legitimate demand. [Govt. Brief at 23]. By distributing a high level of SLC products to its customers, who in turn sell a large amount of SLC products to consumers, Novelty is failing to maintain effective controls against diversion, pursuant to 21 U.S.C.

§ 830(h)(1). Consistent with precedent, the Government asserts that Novelty has a duty to protect against diversion and notes that entities that have distributed a high level of SLC products in the past that exceed legitimate demand have had their licenses revoked. [Govt. Brief at 24]. Failure to maintain effective controls against diversion weighs in favor of revoking Novelty's registration.

d. Novelty Failed to Maintain Accurate Records of its Distributions

DEA performed an audit of Novelty's ephedrine and pseudoephedrine products for the period of December 25, 2006 to July 9, 2007. [Govt. Brief at 25]. Diversion Investigator Lisa Barnhill prepared a computation chart of the audit, which revealed that 15 of the 20 products had overages of 3,696 dosage units to 50,496 dosage units. [Govt. Brief at 25]. Two ephedrine products had shortages of 27,924 and 32,913 respectively. [Govt. 26].

A second audit was done on four of the 20 products originally audited, which revealed an increase in the overage from 7.3 percent to 64.25 percent. [Govt. Brief at 26]. Ryan Polk of Novelty testified as to errors on the part of DEA during the audit, which included failing to take into account 28,800 dosage units of Item 17902 that were returned to Novelty's supplier, failing to take into account 44,000 units of Item 17903 that had been moved to the expired category and 9,300 units of the same item

which were returned by the route sales professionals. [Govt. Brief at 26-27]. Notwithstanding the testimony and supporting documents provided by Novelty regarding its perceived errors of the audit, the Government notes that Ryan Polk signed off on the audit for Item 17903, indicating his agreement with it and could not produce proper documentation supporting his assertion for Item 17902. [Govt. Brief at 26-27].

Given the outcome of the audit, which showed high overages and shortages that is indicative of poor recordkeeping, the Government asserts that Novelty was in violation of 21 U.S.C. § 830(a)(2) and 21 C.F.R. § 1310.06(a).

e. Novelty distributed SLC Products to Retail Outlets that were not Self-Certified under the CMEA

Based upon the inspection of Novelty's records, specifically looking at the addresses of Novelty's customers, DEA Diversion Investigator Barnhill concluded that Novelty was distributing to entities that were not self-certified, as required under the CMEA. [Govt. Brief at 29]. DI Barnhill could not find records of some of Novelty's customers' self-certification documents when she researched the DEA database. [Govt. Brief at 29]. Though Novelty was able to provide documentation supporting the self-certification of the Speedway convenience stores and testified that DEA's findings were not proper, the Government asserts that the actual sales records of

Novelty, which do not support Novelty's claim, are more reliable and should be given due weight. [Govt. Brief].

Notwithstanding Novelty's testimony at trial, the Government stresses that Novelty's inability to keep proper recordation of its customers' self-certification at the time of the inspection is indicative of poor recordkeeping and this weighs in favor of revocation of Novelty's license. [Govt. 32].

f. Novelty Distributed SLC Products in Bottles for Retail Sale after the CMEA Restricted the Sale of SLC Products in Blister Packs

Based on Novelty's records, Novelty sold ephedrine products to three of its customers in bottles in 2007, in violation of the CMEA. [Govt. Brief at 32]. However, during the hearing, Novelty representatives attributed the erroneous sales to coding errors and testified that the items were indeed sold in blister packs, as required by Federal law. [Govt. Brief at 32]. If the sales are attributable to coding error, the Government asserts that Novelty then maintained inappropriate records of its distribution of SLC products, in violation of Federal law. [Govt. Brief at 33].

g. Novelty Distributed SLC Products in Tablet Form for Sale in States Where Such Sales Are Prohibited

Based on Novelty's records, it sold ephedrine in tablet form in Kentucky and North Carolina, both which prohibit such sales. [Govt. Brief at 34]. However, during the hearing, Novelty representatives attributed the erroneous sales to coding errors and testified that the items sold were actually gel caps, and, therefore, there was no violation. [Govt. Brief at 35]. Notwithstanding Novelty's assertion, given the route sales professionals enter the product codes into their handheld computers at the time of distribution and Novelty representatives' claims that they were not sure if some of its salesmen had non gel-cap products in their possession after enactment of the state laws, the Government asserts that due weight should be afforded to the contemporaneous record, as it is more credible than the testimony of Novelty's representatives at the hearing. [Govt. Brief at 36].

Furthermore, the Government stresses that regardless of possible coding errors, as Novelty asserts, Novelty still maintained improper record-keeping of its distribution of SLC products and is, therefore, in violation of Federal law. [Govt. Brief at 37].

h. Conclusion

In light of the above, the Government concludes that it has shown by a preponderance of the evidence that revocation of Novelty's DEA registration is in the public interest. [Govt. Brief at 37].

2. Respondent's Position[33]

a. Generally

The Respondent summarizes its case in favor of continued registration, writing that the preponderance of the evidence has failed to prove: (1) DEA's Charge That Novelty Distributed SLC products from Unregistered Locations; (2) DEA's Charge That 22 Bottles of Ephedrine Products Distributed by Novelty Were Found in a Connecticut Meth Lab; (3) DEA's Charge That Novelty Sells Amounts of SLC products in Excess of Legitimate Demand; (4) DEA's Charge That Novelty's Retail Customers May Have Sold Above CMEA-Allowed Limits; (5) DEA's Charge that Novelty Failed to Account for 60,000 Dosage Units of Ephedrine and Had Overages of 16 Different SLC products; (6) DEA's Charge That Novelty Failed to Maintain Accurate Records; (7) DEA's Charge That

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[33] The Respondent filed a "Consent Motion to File Erratum Correcting Clerical Error in Novelty's Final Brief" on May 5, 2008. I did not file a separate order granting the Respondent's Motion, but I hereby grant the Motion. Further, I note to the parties that I have incorporated the Respondent's corrections accordingly in the summary of the Respondent's position.

From January 1 to July 9, 2007, Novelty Distributed SLC products On 284 Occasions to 35 Retail Outlets That Were Not Self-Certified; (8) DEA's Charge That Novelty Distributed 24-Count Bottles of SLC products In Violation of Federal Law; (9) DEA's Charge That Novelty Distributed Tablet Form of SLC products in Kentucky and North Carolina In Violation of State Law; and (10) DEA's Charge That Novelty Distributes to the Non-Traditional Market. Further, DEA has failed to meet its burden of proof. Lastly, the Respondent asserts that the DEA's immediate suspension has had the perverse effect of actually increasing the risk of diversion of SLC products.

Accordingly, the Respondent concludes that all public interest factors in 21 U.S.C. § 823(h) favor continued registration of Novelty.[34]

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[34] The Respondent has made multiple additional assertions in its brief. Specifically, the Respondent claims that: (1) DEA Violation of Novelty's First Amendment Rights; (2) DEA violated the reasonableness restrictions of 21 U.S.C. § 880 and the warrant issued by the Federal District Court; (3) DEA violated Novelty's Fifth Amendment right to Due Process; (4) Darrell Meador committed an assault and battery; and (5) DEA violated the Administrative Procedure Act (APA) in its action against Novelty. Although considered, I have concluded that these assertions are not appropriately presented to me for a recommended decision. Therefore, I will not go into any greater detail here regarding these allegations. I commend pages 139 to 167 of the Respondent's brief, should the Deputy Administrator deem it appropriate to address these allegations in her Final Order.

Specifically, the Respondent addresses each point in detail as follows:

b. DEA's Charge That Novelty Distributed SLC Products from Unregistered Locations

Novelty asserts that the DEA's charge that it distributed SLC products from unregistered locations is arbitrary, capricious, and does not follow DEA precedent. [Resp. Brief at 96]. The storage units that Novelty used serve as cross docks for the distribution of the SLC products to Novelty's customers and were not used as storage facilities. [Resp. Brief at 96]. The storage units were not warehouses, nor were they Novelty's principal places of business. [Resp. Brief at 96].

Given the storage units are cross docks, they needn't be registered with DEA, and Novelty further asserts that its distribution scheme is safer than other practices which DEA currently permits, including the use of FedEx and UPS delivery companies. [Resp. Brief at 102]. Novelty further claims that it acted in good faith when it filed a suit in federal court seeking a ruling on the enforceability of the DEA letter. [Resp. Brief at 103].

c. DEA's Charge That 22 Bottles of Ephedrine Products Distributed by Novelty Were Found in a Connecticut Meth Lab

Novelty questions DEA's charge that Novelty was the distributor of 22 bottles of ephedrine that were found in a methamphetamine lab in Connecticut. [Resp. Brief at 104]. These bottles were supplied by DMD, a registered supplier of SLC products, who notified DEA that the entire lot of the bottles found, were sold to Novelty. [Resp. Brief at 33-34]. Novelty questions the reliability of the information, given that DEA Investigator Kuzma did not confirm this fact with DMD's records nor did she inquire further if the bottles were diverted from DMD's trucks prior to delivery to Novelty. [Resp. Brief at 34, 104]. Moreover, while Novelty was able to track products within the lot number to two sales representatives, there is no information concerning how many units were in the lot and no confirmation that all the units were sold specifically to Novelty. [Resp. Brief at 37]. Given that Novelty purchased only 24 cases of the lot from DMD, the Respondent asserts that it is doubtful Novelty purchased the entire lot. [Resp. Brief at 104].

Furthermore, in all of the visits by DEA, Mr. Polk did not recall Investigator Kuzma mentioning the issue of diversion of Novelty-distributed products nor did she instruct Novelty to change its distribution methods. [Resp. Brief at 36, 104, 105].

In conclusion, Novelty stresses the lack of evidence concerning this allegation, given that there is no direct proof that the ephedrine bottles found in the meth lab in Connecticut were distributed by Novelty and sold by one of Novelty's customers. [Resp. Brief at 105].

d. DEA's Charge That Novelty Sells Amounts of SLC Products in Excess of Legitimate Demand

Novelty asserts that ephedrine is a legitimate remedy for patients struggling from asthma, especially for those who do not have health insurance coverage. [Resp. Brief at 59-60, 107-08]. Additionally, given the high price of prescription medication, access to ephedrine products is essential. [Resp. Brief at 108].

The price of ephedrine products in convenience stores is attractive to consumers because products are provided below the price of prescription inhalers. [Resp. Brief at 108]. Also, not all pharmacies carry orally-ingested ephedrine, another reason motivating consumers to buy ephedrine products from convenience stores. [Resp. Brief at 108]. While Novelty acknowledges the Government's likely argument that ephedrine's retail price in convenience stores is higher than in pharmacies, making the decision to purchase ephedrine in convenience stores less attractive to legitimate consumers, Novelty maintains that this would therefore make the purchase of ephedrine in convenience stores less attractive to illicit users of

ephedrine. [Resp. Brief at 56-57, 108]. Illicit users would not attain any profit margin by purchasing ephedrine in Novelty's customers' stores, further supporting Novelty's position that it serves the legitimate market. [Resp. Brief at 109].

Novelty further challenges the monthly expected sales value proposed by Mr. Robbin, the Government's expert witness. [Resp. Brief at 109]. Novelty asserts that the expected sales value Mr. Robbin proposes is not supported by any of the data Mr. Robbin uses in his analysis and is based upon many improper assumptions, as further exemplified by the testimony of Dr. Shepherd, Novelty's expert witness. [Resp. Brief at 40-49, 110]. It is, therefore, improper for the DEA to rely upon Mr. Robbin's expected sales value. [Resp. Brief at 110].

While the Government used the high retail price of ephedrine and the monthly expected sales value to show the diversion of ephedrine that Novelty sold to its customers, Novelty maintains that the unreliable testimony and evidence of Mr. Robbin coupled with the price disincentive for manufacturing meth, further indicates the legitimacy of Novelty's distribution of ephedrine. [Resp. Brief at 111].

e. DEA's Charge That Novelty's Retail Customers May Have Sold Above CMEA-Allowed Limits

Novelty states that DEA's allegation that its retail customers may have exceeded the allowable per

person sales limit is not substantiated by evidence. [Resp. Brief at 111]. Novelty asserted that the log book summaries generated by the DEA Diversion Investigators were biased and DEA only visited less than half of a percent of the total stores that Novelty services. [Resp. Brief at 112]. Novelty's customers are large chain convenience stores with high traffic volume, and in the various stores that DEA did visit, there were no violations over the allowable sales allotment. [Resp. Brief at 64-65].

DEA did not confirm the log book entries with scanned data information at any of the stores it visited and DEA did not investigate the purchasers of ephedrine to determine the purported use of the SLC products. [Resp. Brief at 66].

In light of the above, Novelty emphasizes the lack of evidence against Novelty to support DEA's charge that Novelty's retail customers sold in excess of the allowable amount under the CMEA. [Resp. Brief at 111].

f. DEA's Charge that Novelty Failed to Account for 60,000 Dosage Units of Ephedrine and Had Overages of 16 Different SLC Products

DEA's audit performed on Novelty in July 2007 is not accurate, and DEA Agent Lisa Barnhill, who conducted the audit, is not trained in inventory accounting. [Resp. Brief at 75, 113-14].

Novelty provided DEA with full access to the inventory for all items requested by DEA's investigators. [Resp. Brief at 72].

Subsequently, following receipt of the Order to Show Cause (OTC), Mr. Polk, a trained accountant, investigated the alleged unaccounted 60,000 units of ephedrine and the overages of 16 different SLC products, and he determined that DEA had not included several data entries in its audit that were essential for an accurate count. This missing data lead to the erroneous allegation of the missing 60,000 units of ephedrine. [Resp. Brief at 75-76].

After the first audit, Investigator Barnhill performed additional audits, relying upon summary data provided to her by the Respondent's vendors of SLC product. However, she did not examine the vendor's underlying documents to confirm the accuracy of these summaries. [Resp. Brief at 78, 114-15]. Additionally, Investigator Barnhill inspected 12,000 documents and did not account for any potential error rate in the calculations, though she admitted that errors were possible. [Resp. Brief at 78-79].

Given the inherent problems with DEA's auditing procedures here, Novelty maintains that the audit results lack credibility. Therefore, the preponderance of the evidence does not support a finding of overages and shortages based on the inaccurate DEA audit compilation chart. [Resp. Brief at 115].

g. DEA's Charge That Novelty Failed to Maintain Accurate Records

Novelty disputes DEA's allegation that it failed to maintain proper records of the SLC products it distributes. [Resp. Brief at 115]. All documentation is maintained at the Respondent's headquarters in Greenfield, Indiana. [Resp. Brief at 115]. Sales representatives input the amount of SLC products delivered to Novelty's customers on handheld computers and each night this data is sent electronically to the Respondent's headquarters, along with a hard copy of the invoice. [Resp. Brief at 116]. All of Novelty's invoices and necessary documents are stored on a main server and contain the necessary information in compliance with 21 C.F.R. § 1310.06. [Resp. Brief at 81, 117]. Novelty's database allows the Respondent to run reports on specific information, and the Respondent is able to track specific items sold to a convenience store and to compare sales among different stores. [Resp. Brief at 80, 119]. Additionally, Novelty supplied DEA with multiple reports indicating specific information of the SLC items being audited, and supplemented DEA with additional information. [Resp. Brief at 81].

Novelty admitted that the 60,000 unaccounted units of ephedrine were due to a reporting error; however, this was one error out of 300-500 million selling units in the last seven years and represents a very small error rate. [Resp. Brief at 79].

Given Novelty's data collection contains all the necessary information regarding the SLC products it distributes, it maintains that it was not in violation of both 21 U.S.C. § 830(a) and 21 C.F.R. § 1310.04.

h. DEA's Charge That from January 1 to July 9, 2007, Novelty Distributed SLC Products on 284 Occasions to 35 Retail Outlets That Were Not Self-Certified

During the audit, Investigator Barnhill identified the stores to which Novelty distributed and then looked on DEA's internal database of self-certified retailers to determine if each of the retail stores were indeed self-certified. [Resp. Brief at 120]. When she was not able to match up certain stores in DEA's database, she concluded that these specific stores were not self-certified. [Resp. Brief at 83, 120].

However, following DEA's conclusion that Novelty distributed SLC products to non-certified stores, Novelty did its own investigation, contacting each of the identified stores and determining that all were self-certified during the period in question. [Resp. Brief at 122].

At the hearing, Novelty provided evidence that these stores were self-certified and also testified to this fact. [Resp. Brief at 120]. Therefore, Novelty maintains that it did not serve any retail convenience stores that were not self-certified during the period in question. [Resp. Brief at 122].

i. DEA's Charge That Novelty Distributed 24-Count Bottles of SLC Product in Violation of Federal Law

Novelty did not violate federal law by selling 24-count bottles of SLC products. The Respondent noted that the discrepancy was due to a keying error by a sales representative into the handheld computer. [Resp. Brief at 84-85, 123]. Since the error was discovered, Novelty has programmed the software to prevent its sales representatives from entering in products that are no longer in the Respondent's inventory. [Resp. Brief at 123]. Additionally, the Respondent confirmed with the retail convenience stores that these products had not been sold to customers. [Resp. Brief at 123].

j. DEA's Charge That Novelty Distributed Tablet Form of SLC Products in Kentucky and North Carolina In Violation of State Law

Based upon Novelty's own investigation after it received the OSC and the Government's exhibits, the Respondent concluded that there was no such violation on its part. [Resp. Brief at 86, 124-125]. Rather, the sales representative had made a reporting mistake when entering the product information into the handheld computer. [Resp. Brief at 86-87, 124]. Novelty uncovered the error when it went back into its records and the records of its customers, which

showed that Novelty indeed had not sold the tablet form products in the two states. [Resp. Brief at 86, 124]. After Novelty discovered the error, it changed its software to prevent entry coding errors into the handheld computers of products that are prohibited by law. [Resp. Brief at 124].

In conclusion, Novelty maintains that the DEA charge was baseless, given that Novelty established that it had not sold tablet form SLC products in either Kentucky or North Carolina. [Resp. Brief at 125].

k. DEA's Charge That Novelty Distributes to the Non-Traditional Market

Novelty disputes DEA's claim that Novelty sells to "small retail outlets," which indicates the potential for diversion of SLC products. [Resp. Brief at 125]. Novelty's customers are primarily large convenience store chains with a large revenue base and are not liquor stores, small convenience stores, video stores, or "head shops." [Resp. Brief at 88-89, 126]. Novelty supplied these stores with SLC products for legitimate therapeutic purposes, and directly stocked the items in a locked plexiglass case, which it provided to its customers. [Resp. Brief at 126]. Furthermore, Novelty does not use a multilayer form of distribution, but directly distributes the SLC products to its customers. [Resp. Brief at 89, 126]. Additionally, Novelty markets its products for only legitimate

purposes and ensures that its customers only sell SLC products to individual consumers within the prescribed limits, in accordance with the CMEA. [Resp. Brief at 89, 126].

Novelty's customers are not part of the industry that DEA deems the "gray" or "nontraditional" market. Such nontraditional markets are typically comprised of small, non-chain stores that serve the illegitimate use of SLC products. The Respondent's market is not consistent with the "nontraditional" market as defined in Investigator Barnhill's declaration and according to DEA precedent. [Resp. Brief at 88, 125, 127].

l. DEA Has Failed to Meet Its Burden of Proof

Novelty asserts that the Government has failed to prove by a preponderance of the evidence that Novelty violated the law and that its registration should be revoked. [Resp. Brief at 127]. The Government has not proven that (1) the products Novelty distributes have been diverted into the illicit market, (2) the amounts of SLC products that Novelty distributed to its customers were in excess of a legitimate demand, and (3) the legitimate demand of ephedrine is $14.39. [Resp. Brief at 128-29]. Additionally, Novelty notes that, given the two-box purchase restriction by consumers, the cost, and the large amounts of ephedrine product needed to make a single gram of methamphetamine, there is no incentive for illicit

users of ephedrine to go to multiple convenience stores to purchase ephedrine. [Resp. Brief at 129-30].

Five of the eight charges against Novelty are patently false. [Resp. Brief at 130]. First, Novelty did not have overages of 60,000 unaccounted-for units of ephedrine, as DEA's audit suggested. [Resp. Brief at 130]. Second, Novelty did not supply SLC products to stores that were not self-certified. [Resp. Brief at 130]. Third, Novelty did not sell either bottled product or tablet form product, in violation of both federal and state law. [Resp. Brief at 130]. Fourth, Novelty did not permit its customers to sell SLC products over the allowable limit imposed by the CMEA, but rather incorporated safety measures to prevent diversion. [Resp. Brief at 131]. Fifth, Novelty has maintained adequate records of its distribution of SLC products in accordance with DEA regulations, which indicate the date of shipment, the product shipped, the amount shipped, the name and location of the store purchasing the items, and the sales representatives who sold the items. [Resp. Brief at 131-32].

Finally, Novelty disputes DEA's charge that it shipped SLC products from unregistered locations, noting that Novelty distributes the SLC products directly from its headquarters, which is registered with DEA, and uses the storage units as a cross-dock prior to delivery of the SLC products to Novelty's customers. [Resp. Brief at 132]. These units are not used as storage facilities, and, therefore, are not

required to be registered, as DEA alleges. [Resp. Brief at 132]. Furthermore, Novelty maintains that its distribution scheme is far safer than using shipping companies like FedEx and UPS, which DEA permits. [Resp. Brief at 133].

In light of the above, Novelty emphasizes that DEA has failed to meet its burden of proof. [Resp. Brief at 133].

m. All Public Interest Factors in 21 U.S.C. § 823(h) Favor Continued Registration of Novelty

Based upon the five public interest factors DEA considers when assessing whether a registrant should or should not be permitted to maintain its DEA registration, Novelty asserts that all factors weigh in its favor, noting that: (1) It has maintained effective controls to prevent diversion of SLC products, including training of its personnel, keeping proper records which include all the necessary information, and packaging of items to prevent tampering; (2) it has contributed sufficient resources to ensure compliance with state, federal and local laws pertaining to SLC products, as evidence of its personnel training manuals, materials for its customers on self-certification, and a hierarchical structure within the company to ensure compliance with the laws; (3) it has not been convicted under either federal or state laws pertaining to controlled substances or to chemicals; (4) it has been registered with DEA for the

past 10 years, it has not received any warning letters from DEA, and it has a mechanism in place to ensure proper compliance and handling of SLC products; and (5) it has experienced a significant loss of business since the immediate suspension, which will only worsen should Novelty's registration be revoked. [Resp. Brief at 134-37].

In conclusion, Novelty states that all five factors weigh in its favor of it [sic] continued DEA registration. [Resp. Brief at 137].

B. Findings of Law

Pursuant to 21 U.S.C. § 824(a)(4), the Deputy Administrator[35] may revoke a DEA Certificate of Registration of a distributor of listed chemical products if she determines that the continuance of such registration would be "inconsistent with the public interest," as determined pursuant to 21 U.S.C. § 823(h). Section 823(h) requires that the following factors be considered:

> (1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels.

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[35] The Deputy Administrator has the authority to make such determinations pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2006).

(2) Compliance by the applicant with applicable State, Federal and local law.

(3) Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law.

(4) Any past experience in the manufacture or distribution of chemicals.

(5) Such other factors as are relevant to and consistent with the public health and safety.

These factors may be considered in the disjunctive: the Deputy Administrator may properly rely on any one or a combination of these factors, and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. *See D & S Sales,* 71 Fed. Reg. 37,607, 37,610 (DEA 2006); *Joy's Ideas,* 70 Fed. Reg. 33,195, 33,197 (DEA 2005); *Henry J. Schwarz, Jr., M.D.,* 54 Fed. Reg. 16,422 (DEA 1989).

Also, in an action to revoke a registrant's certificate, the DEA has the burden of proving by a preponderance of the evidence that the requirements for revocation are satisfied. 21 C.F.R. § 1301.44(e). The burden of proof shifts to the Respondent once the Government has made its prima facie case. *Thomas Johnston*, 45 Fed. Reg. 72,311 (DEA 1980).

1. Factor One: Maintenance of Effective Controls Against Diversion of Listed Chemicals Into Other Than Legitimate Channels

a. *Physical Security*

First, the record contains no evidence that the Respondent's physical security at its registered location is inadequate. [*See* Finding of Fact ("FOF") 31, 32 for Respondent's physical security measures].

The record also contains evidence regarding the security provisions made for SLC products in the drop off points. Specifically, they are padlocked, self-storage facilities with limited key access. [FOF 54]. These self-storage facilities have varying additional external security for the entire facility. [FOF 55]. Yet the record also shows that the SLC products are not segregated within these drop off point units. Specifically, the storage units do not have separate cages for the storing of the SLC products. [FOF 54]. Should the DEA prevail on its interpretation that these drop off facilities are in fact warehouses under the CSA and its implementing regulations, such security provisions may be inadequate.

b. *Recordkeeping*

A distributor's required records must be readily retrievable.[36] Here, the Respond [sic] had thorough records, but they were maintained in a code known only to Respondent. [FOF 236, 241]. Because of this, the DEA had to request multiple versions of the records until they could actually develop the facts needed to test the Respondent's accountability in handling SLC products. Arguably, this difficulty in actually comprehending the Respondent's records violated the spirit of the requirement that the records be "readily retrievable."

The DEA has previously held that a key method of maintaining effective controls against diversion is to develop and maintain accurate records of listed chemical transactions. Specifically, the regulations provide that "(t)he adequacy of the registrant's . . . systems for monitoring the receipt, distribution, and disposition of List 1 chemicals in its operations" is an appropriate consideration when evaluating the registrant's maintenance of security. 21 C.F.R. § 1309.71(b)(8); *see also OTC Distribution Company v,* 68 Fed. Reg. 70,538, 70,542 (DEA 2003).

Here, the Respondent's sales representatives determine the quantity of SLC products to order per convenience store customer and received a combined

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[36] Specifically, the regulation requires: "The records required to be kept under this section shall be readily, retrievable and available for inspection . . . " 21 C.F.R. §1310.04(e).

shipment once a week for subsequent delivery to the Respondent's customers. The order is shipped to the sales representative, not to each convenience store customer. At the time of shipment of SLC product from the Respondent's warehouse, the Respondent has no idea which of its customers are receiving what amount of SLC product. The only record the Respondent has at that time is the shipping record showing the amount of SLC products shipped to the sales representative. [FOF 30, 39, 53, 84, 88, 91, 93, 104, 109, 113, 120]. The orders are not placed and shipped directly to the Respondent's individual customers, but rather are shipped to the sales representatives who will determine where to deliver them during the course of the delivery route. [*Id.*].

As evidence by the problems encountered in 2002 when the Respondent attempted to track the delivery of SLC products it received from DMD, the Respondent can only track the products to a route and sales representative. When the Respondent attempted to determine what store may have sold SLC products that were found in an illicit methamphetamine laboratory, the Respondent was unable to retrieve that information. [FOF 42, 43-45]. This lack of accountability of SLC product is troubling.

However, the Respondent has taken numerous precautions to justify entrusting its sales representatives with this much authority in choosing where to distribute SLC products. Specifically, the Respondent has instituted a computer inventory control system which requires the sales representative to generate

invoices upon delivery of SLC product, and to order such products from the Respondent's warehouse in this manner. [FOF 9]. Personnel at the Respondent's headquarters ultimately reconcile the sales representatives' sales with shipment and inventory records. The sales representative is required to transmit the day's transactions by computer each night. [*Id.*]. Yet, the Executive Vice President of Sales receives a weekly report only showing SLC product inventories by route. [FOF 10, 41]. Technically, during the intervening timeframe, the SLC product is merely traceable to the sales representative and not to the Respondent's customers.

Next, the DEA asserted that the Respondent's records demonstrated two instances of the Respondent's shipping of SLC products in violation of the law. First, the DEA found in the Respondent's records that the Respondent shipped bottled SLC product in violation of the CMEA. [FOF 139-40]. The Respondent ultimately provided a credible explanation with documentary proof that the bottled SLC product in fact had not been illegally distributed. [FOF 141-43]. However, these recordkeeping errors had not been discovered during the Respondent's monitoring of its own recordkeeping systems.

Next, the DEA discovered, upon reviewing the Respondent's-provided records, that the Respondent had shipped SLC product in tablet form to Kentucky and North Carolina, in violation of those States' laws. [FOF 144-45]. Again, at the hearing, the Respondent produced credible testimonial evidence to support a

finding that these illegal sales in fact did not happen. However, the Respondent acknowledged that the errors did exist in the Respondent's records as supplied to the DEA. [FOF 146].

c. *DEA's Audit*

During the administrative inspection, the DEA conducted a physical inventory count of 20 SLC products distributed by the Respondent. The counts were certified by the Respondent's representatives and the DEA investigators. [FOF 155-57]. The inventory period was from December of 2006 until the close of business on July 9, 2007.

The DEA also requested, and the Respondent supplied, purchase and sales records for the same timeframe for the same 20 SLC products. [FOF 158-59].

Using this data, the DEA prepared an audit computation chart. The audit revealed that the Respondent sold more ephedrine products than it should have had in its inventory (overages) in 15 of the 20 products inventoried. These overages ranged from 576 dosage units to 50,496 dosage units. [FOF 161]. The DEA's computations also demonstrated the Respondent had shortages of two SLC products of 27,924 dosage units in one product, and 32,913 dosage units in the other. [FOF 161].

Subsequently, the DEA contacted the Respondent's suppliers and received purchase summaries.

The suppliers' summaries did not match the Respondent's purchase records[37] for purchases made during the audit time period. [FOF 162]. DI Barnhill recomputed the audit figures using the suppliers' figures and found overages in all four SLC products so affected. These overages ranged from 5,856 dosage units to 275,664 dosage units. [FOF 163]. I do note that the accuracy is further called into question by the fact that the DEA's audit chart included data from BDI, one of the Respondent's suppliers, but this record contains neither BDI's summary of sales nor actual BDI invoices. Therefore, these figures can not be verified. [FOF 162].

At the hearing, the Respondent questioned the accuracy of the DEA's audit results. Mr. Polk credibly testified that, when he attempted to reconstruct the DEA's audit, he noted that the DEA's investigators had failed to use three sets of documents the Respondent had provided to them. Specifically, the DEA had failed to take into account dosage units returned to vendors, data that had been removed from the inventory because of expired or obsolete inventory, and other unspecified documents reflecting miscellaneous transfers or adjustments. [FOF 164-65]. Yet

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[37] I do find it significant in weighing the evidence, that, in the record of this matter, the suppliers' purchase summaries were not supported by invoices. The extent to which those summaries are reliable and actually comport with purchases made and delivered during the audit time frame remains unknown. [FOF 162].

weighing the Respondent's audit evidence, I also note that Mr. Polk's own documents show returns of 57,600 dosage units, but fail to show the dates of these returns and fail to provide any underlying documentation actually demonstrating the transfers back to the vendor. [FOF 166]. Even using the Respondent's own analysis of its documents, the audit still reveals discrepancies. [FOF 165-66].

Therefore, based on the evidence in this record, this audit does not present preponderating evidence either way to assist in analyzing the accuracy of the Respondent's handling of SLC products. However, it strongly supports a conclusion that the Respondent's recordkeeping is not adequate to conduct an effective audit of its SLC products.

d. *Safeguards Levied Upon the Respondent's Customers*

The Respondent asserted, and the record does not refute, that, prior to the immediate suspension, the Respondent was the only distributor of SLC products to its convenience store customers. [FOF 27, 75, 80, 91, 93].

Further, the Respondent implemented a limit on the quantity of SLC products a convenience store may purchase in any single transaction. [FOF 33]. Should a sales representative sell more than this limit to a customer in any single transaction, that representative would receive a written reprimand, and, if it

happened again, may be terminated from his position. [FOF 35].

However, it is troubling that the report created from sales data provided by the Respondent established that sales transactions over the limit occurred 85 times between January and July of 2007. [FOF 36]. Although this number, when placed in the context of the quantity of SLC product sales occurring during this time frame may seem insignificant, the number of times sales occurred above a limit placed by the Respondent still calls into question the deterrent effect of this sales limitation. [FOF 12-16].

Also, as a seemingly direct contradiction, the Respondent's sales representatives receive a 5% commission on the sale of some SLC products. This is higher than commissions paid for other SLC products and for non-SLC products. [FOF 28]. This would seem to provide the sales representatives with an economic motive to sell as much of this product as possible. This incentive, coupled with the somewhat questionable enforcement of the sales representatives' one case limit, causes concern.

Taken together, therefore, the evidence relevant to factor one supports revocation.

2. Factor Two: Compliance with applicable State, Federal, and Local Law

The record clearly demonstrates that the Respondent's personnel have been proactive in remaining

knowledgeable and current regarding the various laws and regulations governing the handling of SLC product at both the State and Federal levels. [FOF 20-23].

a. *Registration of the Respondent's "Drop Off" Points*

The Respondent's only registered location is its headquarters with its adjacent warehouse in Greenfield, Indiana. [FOF 2]. In this case, a key issue in dispute is whether or not the Respondent is required by law to register each drop off point, or the place where it ships SLC products to its sales representatives who subsequently distribute them to the Respondent's customers. The dispute revolves around the interpretation of the following statutory proviso: "A separate registration shall be required at each principal place of business . . . where the applicant . . . distributes . . . list I chemicals." 21 U.S.C. §822(e).

The DEA asserts that the Respondent's conduct in so shipping its SLC products results in the products actually being distributed from the mini-warehouse to the Respondent's customers. Accordingly, the mini-warehouse is required to be a registered facility. [*See* Govt. Brief at 5-8]. By not registering each of those facilities, the Respondent is violating federal law, concludes the Government. In support of its position, the Government cites to *Seaside Pharmaceutical*, 67 Fed. Reg. 12,580, 12,582 (DEA 2002).

The Respondent, however, argues that the SLC products are not stored at the mini-warehouses. Rather, these drop off points are used as a cross dock in the course of the Respondent's shipping the products from its registered location to its sales representatives, who use the Respondent's trucks to deliver the product to the Respondent's customers. [*See* Resp. Brief at 96-103; *see also* FOF 61, 63].

The facts are not in dispute regarding this issue. The Respondent's shipping method is well defined. [FOF 49-58].

However, in May of 2004, the DEA, in a letter written by a DEA Group Supervisor, informed the Respondent that, in given circumstances, a registrant may authorize a sales representative to keep SLC products overnight in a locked secure vehicle. If certain conditions do not exist, then presumably the products did not qualify for this transportation and delivery exemption. The DEA inferred that this letter made it clear that the exemptions did not apply to the Respondent, and therefore the Respondent would have to register each of its "drop off" points. [FOF 60]. Rather than inquire further within the hierarchy of the DEA regarding the meaning of this letter as it applies specifically to the Respondent, the Respondent chose to seek a declaratory judgment from the federal district court concerning the legality of the DEA's interpretation of the Controlled Substances Act and implementing regulations on this point. [FOF 60, 62]. While the court case was pending, the Respondent chose to continue operating its business

as it had prior to receiving the DEA's notice. [FOF 62].

The Respondent's conduct, in ignoring a DEA directive, is not consistent with the requirements for a participant in a regulated industry. Even if the Group Supervisor's interpretation is ultimately found to be incorrect as it applies to the Respondent, the Respondent has a duty to act consistently with the directive until receiving verification that its interpretation of the law is, in fact, correct. The Respondent had alternatives ranging from inquiring within the DEA itself as to whether or not the Group Supervisor's letter actually required the Respondent to register each of its drop off points, to ceasing to use its drop off points while its court case was pending. Choosing to continue to operate in violation of the DEA's directive was not a viable option, however.[38] Therefore, this conduct weighs in favor of revocation of the Respondent's registration.

b. *Self-Certification*

The DEA, using addresses provided by the Respondent's sales records and the DEA's self-certification database, determined that the Respondent sold 1.1 million dosage units to convenience

[38] I choose not to address the statutory interpretation issue in this decision. Since this matter is pending in federal court, and the DEA is actively participating in that forum, I conclude that that is the proper venue for this issue.

store customers that were not self-certified. [FOF 151-52]. The record also shows that the DEA has experienced a back log in compiling and placing self-certification information in its database. [FOF 150]. Also, upon further investigation, Mr. Merlau confirmed that the Respondent's customers were, in fact, self-certified. [FOF 153]. Therefore, I conclude that a preponderance of the evidence does not support a conclusion that the Respondent sold SLC product to convenience stores that were not self-certified.

c. *Post-Suspension Actions*

I also find troubling the Respondent's attempts to work around the constraints levied upon it by the immediate suspension of its DEA registration. Specifically, the Respondent explored the possibility of Respondent's employees working as sales agents for another SLC product distributor, BDI. Specifically, Mr. Green signed a letter dated February 8, 2008, informing his SLC-product customers of the company's inquiry into a proposed sales arrangement between the convenience stores, the Respondent, and BDI. [FOF 47]. However, the record contains no indication that the Respondent asked the DEA if such a business arrangement would be lawful under the CSA or the implementing regulations prior to sending such a letter. Further, the record shows that the Respondent intends to explore ways to sell SLC products to its convenience store customers without actually handling the SLC product. [FOF 48]. Although the arrangement may have legitimacy, the

Respondent still does not seem to understand that it is working in a highly regulated industry when it handles SLC products. Prior to devising and implementing creative business strategies for the sale of these products after its DEA registration has been suspended, the burden is upon the Respondent to ensure its proposed methods of handling its SLC product line comports with the statutory and regulatory requirements.

Taken together, therefore, the evidence relevant to factor two supports revocation.

3. Factor Three: Prior Conviction Record

The record contains no evidence that either the owner of the Respondent or its employees have any criminal convictions related to the handling of SLC products. Therefore, factor three weighs in favor of the Respondent's continued registration.

4. Factor Four: Respondent's Past Experience in the Distribution of Chemicals

The Respondent has been a DEA registrant since 1998[39], and has been a distributor of SLC products since approximately 1984. [FOF 2]. Thus, the Respondent

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[39] The first time a registration application was required to handle combination ephedrine products was in 1997. 21 C.F.R. § 1310.09

has had extensive experience in the distribution of SLC products.

Prior to serving the Order to Show Cause and the Immediate Suspension Order in this matter, the Respondent had not been informed by the DEA of any incidents of diversion of its SLC product. [FOF 29]. Except for the Raber letter, the Respondent also was never informed by the DEA of any statutory or regulatory violations. [FOF 29, 60, 123, 125, 131, 137, 148]. Lastly, the DEA renewed the Respondent's registration annually between 1998 and 2007. [FOF 2]. Given this nine year history of compliance, I find that the evidence relevant to factor four supports a remedy less severe than revocation of the Respondent's registration would better serve the public interest.

5. Factor Five: Such Other Conduct Which May Threaten the Public Health and Safety

The record clearly establishes that methamphetamine may be manufactured using over-the-counter ephedrine and pseudoephedrine products. [FOF 191-92, 195-96]. The parties do not dispute this fact and do not dispute that illegal methamphetamine is a major drug problem in the United States. The DEA, however, seems to be trying to remedy this problem by restricting or eliminating the availability of such over-the-counter products by removing the distributors of SLC products to convenience stores from the

market place. This action is based upon the premise that distributors are placing excessive amounts of SLC products into the market place by selling such products to their convenience store customers. Further, the DEA's premise also seems to be that these "excessive" amounts are being diverted to the illicit manufacture of methamphetamine. This record, however, calls such an analysis into question.

a. *Excessive Sales*

Another key issue in dispute is whether or not the Respondent sold SLC products in such quantities that the only economic and statistically supported conclusion that can be drawn is that the product is being diverted for illicit use.

1. Legitimate Demand

The record demonstrates that there may be a legitimate, medical need for over-the-counter ephedrine products. Specifically, Dr. Pacin, an expert witness in the areas of the treatment of asthma, credibly described how ephedrine products assist in relieving the symptoms of a patient experiencing an asthma attack. [FOF 167]. For a patient experiencing an asthma attack may find relief in easing bronchial constriction produced during the attack by ingesting ephedrine products. [FOF 171, 176]. In fact, Dr. Pacin credibly testified that, when he was first treating asthmatic patients, ephedrine and combination ephedrine drugs

were the primary drugs used to treat such conditions. [FOF 177; *see also* FOF 178].

Dr. Pacin also credibly testified that physicians no longer rely upon ephedrine products for the treatment of asthma. Dr. Pacin advises his patients to use prescription medications to control and to prevent asthma attacks. [FOF 182]. Such prescription drugs, which include inhalers, are quite expensive, however. Even with insurance, a patient may have a $50.00 to $75.00 co-pay for each inhaler. [FOF 183]. Therefore, the lack of money may be a barrier to an asthmatic patient's purchasing such medications, especially if they are uninsured. [FOF 183, 185].

A second barrier to using prescription inhalers is the difficulty many patients experience in using them. Dr. Pacin found that 89% of patients using inhalers do not use them correctly. [FOF 184].

Lastly, asthmatic patients who are not seeing a physician for treatment, or may be traveling or otherwise unable to have access to prescription medications, will look to over-the-counter medications for symptom relief. [FOF 185, 188-89].

The record also demonstrates that ephedrine products are being used by hospital workers and truck drivers to stay alert on their jobs. [FOF 104, 110, 128]. The record contains no evidence proving that such use violates any statutory or regulatory provisions, however.

Thus, the record supports a finding that there is a need for such over-the-counter ephedrine products. [*But see* FOF 190]. The question remains, however, as to the amount of over-the-counter SLC products needed to meet this need. [*But see* FOF 190].

The record contains evidence of repetitive purchases of SLC products by a few individuals identified by the DEA's review of the logbooks at various convenience stores. [FOF 79, 79, 81, 86, 106, 117-18, 123, 125, 131-32]. However, with only one exception, the record contains evidence that these customers did not violate the thresholds for lawful purchase of these SLC products. [FOF 115, 117, 123, 126, 131; *but see* FOF 92].

2. Supply

I find it significant that, consistent with the experience of a prior law enforcement officer and criminal defense attorney, at least in the Shenandoah Valley area, convenience stores are not the primary source of SLC products for illicit manufacturers of methamphetamine. Rather, in his experience, the source was big-box stores that sold the SLC products at a discount price. [FOF 194].

To further raise doubt as to the use of the convenience store as a source for SLC products, the record demonstrates that, depending on the strength of the individual SLC product, a methamphetamine laboratory would need between 104 and 248 ephedrine

pills to produce one gram of methamphetamine. [FOF 196]. Using the Respondent's customer's range of retail prices for the Respondent's SLC products, it would cost between $50.00 to $144 to produce one gram of methamphetamine. [FOF 18, 196]. The record also shows that the street price for a gram of methamphetamine was between $20 and $50. Thus, using the Respondent's product to manufacture methamphetamine makes little monetary sense.

Further, the DEA did a small canvass of local drugstores regarding their handling of ephedrine products. A number of drugstores verified that they do not carry such products. [FOF 95, 07, 99, 107, 108, 112, 121; *but see* 94, 96, 98, 100, 102, 112, 119]. The DEA infers from these facts that there is a very limited demand for these products. Yet, the Respondent just as credibly infers that this limited supply increases the demand for such products; a demand that is being filled by the convenience store industry.

3. Statistical Evidence

The record contains extensive evidence concerning Mr. Robbin's statistical analysis to reach a conclusion that a convenience store is expected to sell no more than $14.39 worth of SLC products per month. [FOF 198-202; *see also* the Appendix of this opinion]. Dr. Shepherd, an expert witness in the areas of statistics and applied statistics, found major flaws in Mr. Robbin's statistical methodology. [FOF 205-19; *see all* the Appendix to this opinion]. These flaws resulted in

raising fundamental concerns about the reliability of Mr. Robbin's analytical process, and, thus, his ultimate opinion.

I find that the Government has not proven by a preponderance of the evidence that a convenience store's expected sales of SLC product is $14.39[40] or less per month. Therefore, based on this record, I do not infer that any convenience store that sells more than $14.39 worth of SLC product per month is selling such product to individuals who will divert it to the illicit manufacture of methamphetamine.

I note, however, that such a conclusion does not end the concern about excessive sales of SLC products to convenience stores. The Government argues that it has met its burden of proving that the Respondent's sales figures for SLC products were excessive by merely looking at the numbers and speculating that such numbers are not justified by legitimate demand.

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[40] Logically, I also have trouble with the DEA's inference using these basic mathematical justifications. First, the retail selling price of the Respondent's 24-count SLC product ranges from $9.99 to $14.99 per package. Thus, using $14.39 per month as the expected sale, the DEA is asserting that any convenience store which sells two or more packages of 24-count SLC product in a month is making excessive sales of this product. Extending the DEA's reasoning, therefore, any SLC product distributor who has convenience store customers selling at retail two or more 24-count SLC product has engaged in business with customers who will make these products available to illicit methamphetamine cooks. This inference, also, is not supported by this record.

I acknowledge that the record demonstrates that the Respondent sells an approximate monthly average of $640.00 in SLC products to its convenience store customers, with the majority of the sales being of ephedrine-containing products. [FOF 18]. Yet, given the total business this Respondent's convenience store customers generate, I find that the record does not justify finding that this number, in this context, proves by preponderating evidence that such sales are "excessive." [FOF 14].

The interest of the public in ensuring that SLC products are not diverted into the illicit market is paramount; however, this interest also needs to be balanced against the interests of the registrant. The Government has the burden to prove that the Respondent's sales are in excess of the demands of the legitimate market; however, the record demonstrates that the expected monthly sales value that the Government relies upon – $14.39 – to justify its position is flawed and not credible. Therefore, there is no legitimate sales figure in the record by which the interests of the public and the interests of the registrant can be measured.

While the Respondent's sales to many of its customers might seem large, to infer diversion without a legitimate monthly expected sales figure by which to compare the Respondent's transactions, is too large of a leap. Such a conclusion, I find, is without justification.

Taken together, therefore, the evidence relevant to factor five supports a remedy less severe than revocation of the Respondent's registration to protect the public's interest in keeping available a supply of ephedrine products for legitimate use.

C. **Other Matters to Consider**[41]

The DEA has consistently held that the Deputy Administrator, in exercising her discretion in determining the appropriate remedy, must consider all of the facts and circumstances of a particular case. *See Martha Hernandez, M.D.*, 62 Fed. Reg. 61,145 (DEA 1997) and subsequent cases citing this final order.

The Respondent has demonstrated a willingness to comply with the laws and regulations governing the distribution of SLC products. First, the Respondent takes a proactive role in ensuring its customers are self-certified. It has developed a training program and distributed that program to its convenience store customers. [FOF 154].

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[41] In an order following an interlocutory appeal in this matter, the Deputy Administrator noted that the Supreme Court has issued opinions that "cast serious doubt on the notion that the exclusionary rule applies in administrative proceedings." [Denial of Interlocutory Appeal at 3]. Given this view, I have declined to address the issues raised by the Respondent regarding the execution of the search warrant and related events. However, I have made a factual record regarding those events in case the Deputy Administrator wishes to address those issues in the Final Order in this case.

Next, the Respondent provided its convenience store customers with the logbooks they would need to remain in compliance with the CMEA. Although not authorized to review the contents of the logbooks, the sales representatives confirm that the logbooks are in place at the store and are being used by the store's employees. [FOF 40, 199]. Also significant, the logbooks oftentimes contained a written reminder that the convenience stores' employees should comply with the sales restrictions in place pertaining to these SLC products. [FOF 90, 105, 124].

The Respondent also provided its customers with lockable, plexiglass display cases for the display and sale of SLC products. [FOF 72, 197]. The record demonstrates that the Respondent's customers were, in fact, using these cabinets. [FOF 93, 104, 109, 120, 124, 127, 129, 197]. The Respondent credibly testified that it also provided its convenience store customers with stickers to place on the display cases, reminding store personnel of the limited number of SLC products authorized per transaction and to use the logbooks to record each sale. [FOF 197].

After the implementation date of the CMEA, the Respondent acted to remove the non-complying SLC products from its customers' shelves and properly dispose of the products. [FOF 198].

I also find it noteworthy that when the DEA brought the recordkeeping errors regarding the illegal selling of tablet SLC products and bottled SLC products to the attention of the Respondent, the

Respondent investigated the records, identified a reasonable reason for the errors, and acted to correct those errors by upgrading its computer system. [FOF 149, 200-02].

V. RECOMMENDED RULING

This case is about perceptions and interpretations of facts.

1. Although the Respondent's records appear to reveal significant overages and shortages of SLC products from the DEA's audit, the Respondent credibly and adequately minimized those figures to a more acceptable margin of inventory error after analyzing its records and making its own audit findings.

2. Although the records appear to indicate that the Respondent improperly sold tablets and bottled SLC products, and sold SLC products to stores that were not self-certified, the Respondent's investigation and explanation of the facts involved in those transactions were credible. Also, the Respondent's actions to upgrade its computer system demonstrated the Respondent's intentions to comply with the DEA's statutes and regulations. [FOF 225].

3. Although the DEA conducted a small canvass of local drugstores regarding their handling of ephedrine products and concluded that there is limited demand, given that a number of these drugstores do not carry ephedrine products, the Respondent credibly inferred that this limited supply increases

the demand for such products; a demand that is being filled by the convenience store industry. [FOF 95, 97, 99, 107, 108, 112, 121; *but see* 94, 96, 98, 100, 102, 112, 119]

4. Although the Respondent's actions appeared to blatantly disobey a DEA directive in the Raber letter, its actions to seek judicial interpretation were legitimate. However, the Respondent was not entitled to ignore that letter and not act in accordance to its directive, while it awaited a decision as to the proper interpretation of the regulations. This lack of compliance in the interim continues to cause concern.

Yet, the DEA's Raber letter was issued in 2004, and the DEA continued renewing this Respondent's DEA registration through 2007. Except for the Raber letter, this Respondent had no notice from the DEA of any violations until the Immediate Suspension Order was served in 2008. Thus, the Respondent has not been given an opportunity to remedy the flaws identified by the DEA in this action. These remedies include: (1) Developing a recordkeeping system that results in "readily retrievable" records available for DEA's review to support any audits or other accountability determinations the DEA deems necessary to protect the public interest; (2) developing a means to assist its convenience store customers to utilize the data they collect in the logbooks to identify frequent purchasers and to take appropriate action; and (3) developing with the DEA an economically viable shipping procedure that also addresses the DEA's concerns for SLC product accountability.

Given this Respondent's 10 year history of compliance, as evidenced by the DEA's continued registration, and its financial commitment to compliance, as evidenced by its rework of its hand-held computer system to better track inventory, totally revoking the Respondent's registration in 2008 does not seem consistent with prior agency action concerning this Respondent. The statute and regulations give the Deputy Administrator a panoply of options available besides revocation. Based on this record, I conclude that this is a case where teamwork between the DEA and this major distributor would further facilitate the public interest.

Therefore, I recommend that the Deputy Administrator not revoke this registrant's registration. Rather, I recommend the Deputy Administrator use her discretion to levy compliance requirements upon the Respondent to a degree that would satisfy the DEA that this registrant is operating [sic] with the DEA to protect the public interest. Such compliance requirements would also clearly communicate to this Respondent that compliance is necessary first, even if the Respondent chooses to subsequently challenge the DEA's interpretation of a statutory or regulatory provision.

Dated: May 21, 2008

/s/ Gail A. Randall
Gail A. Randall
Administrative Law Judge

APPENDIX

I. Testimony of Jonathan Robbin

A. *Mr. Robbin's Background*

1. Mr. Robbin is the founder of Ricercar, Inc., which conducts business in the areas of marketing research and applied statistics and serves primarily commercial enterprises and government entities. [Tr. 163-64; Govt. Exhibit 25 at 1].

2. Mr. Robbin has participated in approximately 29 civil and criminal government proceedings. [Tr. 202]. Of these total proceedings, Mr. Robbin has been qualified as an expert in three of them, including a DEA administrative proceeding. [Tr. 202-03].

3. Prior to the completion of his graduate studies, Mr. Robbin transitioned to the business sector, where he specialized in developing systems to process psychometric data. [Tr. 167]. Psychometric data involves questionnaires that are collected by research departments and advertising agencies, where consumer behavior is analyzed with the overall objective of improving the return of investment of advertising dollars. [Tr. 167]. Some of the advertising clientele included Grey Advertising, Benton & Bowles, Young and Rubicon, and Mosteller. [Tr. 167]. These advertising agencies served consumer goods companies, such as Bloch Drug, General Foods, and Warner & Lambert. [Tr. 167].

4. Mr. Robbin later started to contract directly with some of these listed companies and also for government entities, where his focus was programming large computer systems to process and organize data and also to do statistical research on the collected data. [Tr. 168-69].

5. In regards to studying retail marketing, consumer consumption specifically, Mr. Robbin began to focus more on this area as an entrepreneur and developed various systems that would aid businesses in determining where to conduct business geographically, including the division of franchises and dealerships and sales routes. [Tr. 169-70]. Along these lines, Mr. Robbin's work included aiding state lottery entities in deciding where to locate their terminals in stores, mainly convenience stores, and also deciding what games to offer at the stores, given the population of the area. [Tr. 170].

6. Mr. Robbin has also been involved in assessing the distribution behaviors of different retail entities. [Tr. 170]. To this end, Mr. Robbin amasses public data that deals with the nation's retail infrastructure, specifically the economic census of the United States Census Bureau ("Census" or "economic census"). [Tr. 170].

7. With regards to DEA's approach to its distribution cases, Mr. Robbin credibly testified that he has dealt with data from different states across the country, including data from Oregon, Washington, California, Nevada, Missouri, Kansas,

Indiana, Florida, Tennessee, Texas and Oklahoma. [Tr. 396]. Regionally speaking, the only area he has not focused on has been New England. [Tr. 397].

B. Data Reports Used by Mr. Robbin in his Analysis

8. The Census is taken every five years and collects data relating to all retail and service entities in the United States. [Tr. 170-71]. While the Census does not obtain a 100 percent response, it does provide a fairly accurate portrayal of the various industries in the nation and their overall function. [Tr. 171][42] However, Mr. Robbin could not state specifically what percentage of convenience stores actually responded to the Census.[43] [Tr. 476, 477].

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[42] Mr. Robbin stated that the Census Bureau has procedures to correct for non-reporting entities, so that the published census is a complete representation of the entire industry that is being studied. [Tr. 513]. Given the Census accounts for missing data, Mr. Robbin stated that it is common practice to rely upon the Census data. [Tr. 514].

[43] When asked, Mr. Robbin stated that he did not know whether any of Novelty's customers had responded to the Census, given that individual census information is confidential. [Tr. 487, 490, 491-92]. Though Mr. Robbin does not know whether Novelty's specific stores actually responded to the census (a fact to which the Government agreed to stipulate [Tr. 491]), I do not find this to be of any detriment to his report. Given the purpose in statistical analysis is to ensure that a proper sample of the industry is represented in the data used, the focus should not necessarily be on individual stores per se

(Continued on following page)

9. The business establishments in the United States are classified under the North American Industrial Classification System ("NAICS"). [Tr. 171]. With regards to the retail industry in particular, there are many different classifications that deal with the various items sold and the different activities that characterize the sector. [Tr. 172].

10. The retail activity reported is very detailed and is made available to the public, both in raw data form and through tables and publications prepared by the Census Bureau. [Tr. 172-73, 302]. The economic census obtains information for the retail sector from questionnaires filled out by the owners of retail businesses. [Tr. 173]. Within the retail industry, retail stores were broken down into different sections based on the kind of business and the specific products sold by the business. [Tr. 173-74].

11. The retail industry finds the economic census data very helpful in assessing market share, profitability of activities, and overall competition and opportunity, among other factors. [Tr. 175].

12. Nonprescription drugs are classified in NAICS under products and services code 20160. This category is listed as Health and Beauty Care products and includes a panoply of health and

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but rather on if a proper sampling of the different types of convenience stores that exist within the industry is represented in the data used.

beauty care products. [Tr. 302; Govt. Exhibit 25A at 1]. However, code 20162, which is a subcategory of code 20160, denotes only nonprescription drugs. [Tr. 302; *see* Govt. Exhibit 25B at 2]. Nonprescription drugs, as defined by the Census Bureau, include over-the-counter packaged medicines for various illnesses or symptoms, where a purchaser does not require a doctor's prescription. [Tr. 309]. An example is ephedrine guaifenesin. [Tr. 310].

13. The categories and subcategories of 20160 and 20162 are mutually exclusive NAICS codes; however, the merchandise line is not mutually exclusive. [Tr. 303]. Therefore, according to Mr. Robbin, to properly estimate the prescription drug data, he must estimate how much of the merchandise in code 20160 is attributable to nonprescription drugs. [Tr. 303]. Mr. Robbin testified that both codes need to be considered.[44] [Tr. 328].

14. Retail convenience stores also may look to trade associations for business decisions. For example, there is the National Association of Convenience Stores ("NACS") trade association. [Tr. 178]. One of the undertakings of associations is to collect data from the industry which it is servicing and then analyze the data for its members. [Tr. 178]. The NACS report is

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[44] The Census does not break down nonprescription drugs further to indicate ephedrine and pseudoephedrine purchases separately. [Tr. 495]. As Mr. Robbin credibly testified, this specific type of data is not available. [Tr. 496-97].

relied upon by those within the industry, as it is useful in informing convenience store operators of trends, what merchandise is or is not selling, and the expected gross margins. [Tr. 332-33; Govt. Exhibit 23].

15. According to the NACS report, there are approximately 140,000 convenience stores in the country. [Tr. 238; *see* Govt. Exhibit 23]. NACS represents the chains and larger convenient [sic] stores; however, "mom-and-pop" convenience stores or small stores are not represented in the survey. [Tr. 339]. To correct this, NACS has accessed a proprietor list that includes all convenience stores in the country, and from that, NACS has interviewed an unbiased sample of small stores. [Tr. 340]. By doing this, Mr. Robbin stated that the overall survey is then a good indicator of explaining the industry's market trends and "operating characteristics," including the small convenience stores. [Tr. 340].

16. The sale of nonprescription drugs is included in the Health and Beauty Care category in the NACS report; however, this category is further broken down into a Health and Beauty Care – Cough and Cold Remedies subcategory. [Tr. 341-42; *see* Govt. Exhibit 25B at 2]. Ephedrine guaifenesin would fall into this subcategory. [Tr. 342]. Other products in this subcategory would include, for example, cough syrups, allergy and sinus remedies, and Tylenol. [Tr. 343].

17. Mediamark Research Incorporated ("MRI") is a company that publishes reports surveying the demand side of consumption and is one of the few surveys that focuses on consumers. [Tr. 179, 499-50]. This is the opposite of an economic census, where the focus is on the supply side. [Tr. 179]. MRI's survey garners approximately 50,000 respondents and is a national survey that covers basically the entire base of consumer goods. [Tr. 182, 517]. MRI's survey is very detailed, and data is collected pertaining to specific brands of items purchased, package sizes, and the form of the product (e.g. tablet, spray, liquid). [Tr. 500-01]. The survey also indicates where purchases were made. [Tr. 501]. Mr. Robbin is able to utilize the MRI software to isolate the categories and codes that he is analyzing and to see the response rates for these categories. [Tr. 518-19]. Because part of the survey is administered person-to-person, the survey itself is more accurate and Mr. Robbin testified that the MRI survey is a good resource indicating the demand side of consumer products. [Tr. 519-20].

18. Information Resources Incorporated ("IRI") is a company that focuses on data collection that measures the buying of goods at the point of sale. The data is collected when the goods purchased are scanned using a UPC code or bar code located on the item. [Tr. 181, 500, 521]. The data is then sorted out by computer systems, where the buying rates of different goods are measured. [Tr. 181]. A good example of IRI information scan data is the grocery retail industry, where a multitude of various

items pass through the point of sale, including over-the-counter drug merchandise. [Tr. 184].

19. IRI data is supplied to the public for a fee. [Tr. 522]. Public users of the data provide IRI with areas that they are interested in and IRI then provides the users with a fee that is relative to the amount of information that is being sought. [Tr. 522].

20. Both MRI and IRI data are objective-based surveys, given that they are not seeking to service a particular industry. [Tr. 523]. Therefore, the reports are not slanted to favor the industries that support and rely upon them. [Tr. 523].

21. With MRI and IRI data, Ricercar, Inc. honed its expertise in analyzing the data mainly in the 1960s and 1970s, where it worked as a contractor for the government. [Tr. 184]. Economic government agencies with which Ricercar, Inc. contracted included the Bureau of Labor Statistics, the Office of Economic Opportunity, the Bureau of Economic Analysis, and the Census Bureau. [Tr. 185].

22. Mr. Robbin has used the economic census data extensively in his work and has analyzed the data within. [Tr. 198-99]. Mr. Robbin credibly stated that, given his work with the economic census, he is very familiar with the collections of research products that distinguish the retail industry. [Tr. 199].

23. Mr. Robbin credibly testified that his work focusing on target marketing, where he uses the economic census and other data, such as

MRI and IRI, provide sufficient information to make dependable predictions or conclusions regarding the traditional or non-traditional line of items for a specific store and the profitability of a particular item in a given store. [Tr. 202].

24. The first study Mr. Robbin prepared for DEA was in 2001 and he used the 1997 economic census data, the most recent economic census data at that time, to prepare the report. [Tr. 235]. The most current economic census available was published in 2002, and Mr. Robbin has updated the data he used to prepare subsequent reports accordingly. [Tr. 235]. The Census is published every five years and the next Census being processed is for 2007. [Tr. 235].

25. Using the various data, all which is publicly available, Mr. Robbin stated that he came up with an expected monthly sales value of $14.39 for ephedrine products in convenience stores. [Tr. 414-17]. This figure was first calculated in September 2007, but Mr. Robbin testified that there have not been any significant changes in the market trends for ephedrine products that would alter his expected monthly sales estimate for January 2008. [Tr. 419-20].

26. To calculate the expected sales value, Mr. Robbin testified that he observed the percentage of sales as a function of total sales. [Tr. 468]. He further stated that he accessed MRI data in his calculation of the expected sales value. [Tr. 469].

27. Mr. Robbin testified that he did not use a multivariate approach in arriving at the $14.39

expected monthly sales value for ephedrine, stating that it would have been inappropriate to do so.[45] [Tr. 454]. Likewise, he stated that he did not consult any consumer-based surveys in his analysis, surveys that would indicate the reasoning behind a consumer's purchase, [Tr. 466].

28. Mr. Robbin stated that in his expected monthly sales analysis, he imputed data from convenience stores without gas pumps to convenience stores with gas pumps. [Tr. 475].

C. *Data Research and Statistical Approach in Analyzing Data*

29. Quantitative research is an observational form of research that uses hard data to make decisions and focuses on reality and not the

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[45] Mr. Robbin stated upon cross examination that he did consider multiple variables, as noted in his declaration (Govt. Exhibit 25). Such variables he considered include observed volumes of sales within the industry, category of goods, and percent sales within the categories. [Tr. 471]. Mr. Robbin stated that he did not take into account the variability of store size in his analysis because convenience stores are well distributed in terms of size. [Tr. 472]. Mr. Robbin stated he also did not take into account geographical location in his analysis because this variable is not significant when looking generally at the convenience store industry for the expected sales value. [Tr. 473-74]. Mr. Robbin also stated that he did not take into account convenience store hours or marketing efforts of stores in his analysis because in a large-scale focus, such variables are rendered meaningless. [Tr. 474].

theoretical. [Tr. 187, 189]. The data that comes in must be analyzed as it is presented and the measure of success is quantitative in nature. [Tr. 187, 188]. That is, given the hard data that is collected, the focus is on how successful the business was in predicting the outcome. [Tr. 189].

30. Market segmenting refers to the separating out of consumers into various groups relating to the sale of particular goods. [Tr. 190]. Market segmenting analysis can be very helpful when there is increased partitioning of consumer groups and different variables are introduced into the analysis. [Tr. 190]. When this is done, businesses are able to identify certain consumer segment groups that are more likely to buy their goods than others. [Tr. 190].

31. Target marketing refers to businesses focusing their marketing efforts on a specific segment of the population that is most likely to respond. [Tr. 196].

32. Mr. Robbin has spent approximately 40 years of his career working the areas of target marketing and developing segmentation systems, servicing a wide variety of industries ranging from the banking industry to the United States Army recruitment. [Tr. 197-98].

33. Mr. Robbin explained his use of the word "traditional" in describing a particular market. [Tr. 200]. "Traditional" in this sense refers to a typical place where an individual would go to purchase a specific item. [Tr. 200]. The individual goes to that store because he knows that he

will find the product he needs or wants. [Tr. 201].[46]

34. The mean and median tabulations in statistics are measures of central tendency. [Tr. 238]. The mean signifies the average variable, whereby the sum of all variables are divided by the total numbers of cases observed. [Tr. 238-39]. While the mean calculation is an important statistical measure, it does not account for outlier variables, but rather accommodates outliers into the calculation. [Tr. 239]. By doing this, the mean might not provide an accurate assessment of the population or group being observed, because it is not accounting for the outliers. [Tr. 239]. The median statistic, on the other hand, does a better job at accounting for outliers, given that the median represents the point in the distribution of a variable where half of the observed cases lie above and below the point. [Tr. 239].

35. The standard deviation measures variation. [Tr. 370]. In a normal distribution curve, which is a set of cumulative probabilities of outcomes, the standard deviation indicates how far the observed value is from the mean value. [Tr. 370]. The standard deviation denotes the variation or spread of the values. [Tr. 370].

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[46] The use of the term "traditional" and "non-traditional" markets is not one that Mr. Robbin states he established; however, he did not point to any authoritative sources that use these terms. [Tr. 478-81].

36. A Z-score represents the number of standard deviations from the mean, which a given value assumes. [Tr. 242]. What the Z-score indicates is the probability of the difference between the observed and mean value. [Tr. 243-44]. Applying the Z-score analysis to the convenience store industry, the Z-score will show which stores are normal in terms of their sales and which are abnormal, and the probability of the store(s) abnormality. [Tr. 244]. The Z-score aids in assessing the significance of the observed value. [Tr. 371].

37. To calculate the Z-score, one takes the difference between the mean and the observed value and then determines how many standard deviations the observed value lies from the mean. [Tr. 241]. So, with a mean of, for example 50 and an observed value of 60 and a standard deviation of 5, one would determine that the observed value (60) lies two standard deviations above the mean of 50. [Tr. 242].

38. In a normal distribution curve, one standard deviation from the mean would capture about 68 percent of the cases; however, in statistical analysis, the preference is to look at two standard deviations from the mean. [Tr. 373-74]. At this point, about 95 percent of the cases are being captured. [Tr. 374]. At three standard deviations, the cases at the very end portions of the distribution curve are being captured, and the curve at the tails tend further toward zero. [Tr. 375]. What this indicates is a very low chance or probability of the observed event occurring. [Tr. 375].

39. Statistical analysis is the application of statistical reasoning and methodology that is used to interpret and explain the observed data. [Tr. 293]. In doing so, certain characteristics of the variables, both individually and in the aggregate, are assessed to come to conclusions. [Tr. 293]. Statistical reasoning, therefore, applies these conclusions to the industry at-large and, given the sample observed, makes generalizations as to what should be expected within the industry. [Tr. 293].

40. In statistical analysis, multivariate statistics is a form of analysis that takes into account more than one variable to make a prediction or classification of an event or objects. [Tr. 176, 291]. Using multiple variables enables a more accurate prediction and stronger outcome and assists in ensuring there are no misleading conclusions. [Tr. 176, 291-92]. Multivariate statistics, when properly controlled, may explain up to 80 percent of the variation of the observable fact being measured. [Tr. 177].

41. The gross margin can be defined as the dollars that are left over after the cost of goods and other costs are removed from the wholesale price. [Tr. 366].

42. The term "markup" can be explained as the amount of money over the wholesale price of the good that is bought by the retail customer. The retailer purchases the item at wholesale but then marks up the item to include the profit and other costs the retailer must take into account. [Tr. 366].

D. Mr. Robbin's Findings of CBS Wholesale's Sales of List I Chemicals

43. Mr. Robbin prepared an analysis for an earlier DEA proceeding involving CBS Wholesalers ("CBS"), a wholesale distributor company which served customers in Georgia and South Carolina. [Tr. 223-24]. The Government requested that Mr. Robbin analyze data contained in invoices of CBS during a three-month period, which included approximately 454 different transactions CBS made with its customers, which consisted of 42 stores. [Tr. 224-25, 297].

44. Specifically, Mr. Robbin was asked to compare the actual sales of CBS against the expected sales he calculated based on the type of customers of CBS and the type of goods it sold to these customers. [Tr. 225]. Actual sales figures were noted in CBS' invoices, showing the sales between it and its customers. [Tr. 298].

45. To tabulate the expected sales, Mr. Robbin used the economic census data and other data sources, such as MRI and IRI. [Tr. 226, 299].[47] The expected sales calculations represented the likely level of sales within the industry. [Tr. 299]. After calculating the expected level of sales within the industry, Mr. Robbin then

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[47] For the MRI data, Mr. Robbin stated that it was not part of the report itself or appended to the report; however, he did access MRI data to assess what portion of the cough and cold category that was listed under the Health and Beauty Care category in the NACS report could be attributed to ephedrine-based products. [Tr. 516-17].

compared CBS' actual sales with the expected sales to see if the figures were similar or if there was some disparity between the figures, and if so, to then explain the difference. [Tr. 299].

46. Using the data, Mr. Robbin ascertained what the expected amount of sales would be of convenience stores, given its general makeup of goods sold. [Tr. 226]. To do this, he compared real sales of CBS' customers with the expected value of sales when taking into account the entire spectrum of the convenience store industry. [Tr. 226-27]. Mr. Robbin first took the actual sales figures of each of CBS' customers and then used these real figures to generate retail sales figures by taking the gross margin or sales found in the National Association of Convenience Stores' ("NACS") industry publication. [Tr. 227-28, 297].

47. Sales observed were for the entire convenience store industry and from this data, Mr. Robbin was able to first deduce whether CBS' sales were consistent with what would be expected for sales of non-prescription drugs within the industry. [Tr. 228]. Mr. Robbin then used data from other sources to see whether CBS' sales were in line with the proportion of sales that reflected the sale of over-the counter drugs containing ephedrine hydrochloride. [Tr. 228]. Finally, an actual value was established which enabled Mr. Robbin to then assess the probability of the observed sales with the actual sales. [Tr. 229].

48. Mr. Robbin further assessed the variation of expected sales from a regional standpoint compared to a national standpoint and found that there was very little variability. [Tr. 229-31].

49. When preparing the report, Mr. Robbin looked at the variation among the convenience store industry, given that these stores vary in size and services offered. [Tr. 236-37]. Focusing on individual convenience stores enabled Mr. Robbin to assess whether the variation among the stores affected his findings. [Tr. 237]. Then, Mr. Robbin also looked at the variation of stores within different geographical areas. [Tr. 237]. Geographically speaking, Mr. Robbin testified that more of the variation is in metropolitan areas than other geographical locations; however, more variation exists when focusing at the individual level and separating out the different types of convenience stores. [Tr. 237-38].

50. Though multivariate statistics ensure a more precise predication, Mr. Robbin stated that such an approach is not necessary to the analysis at hand, where simply comparing the variable to the mean and noting the variance is sufficient to assess the significance of the relationship and whether or not the observed variables occurred by chance or are truly different. [Tr. 291-92].

51. When looking at the convenience store industry, which includes gasoline stations with convenience stores, in-store sales are defined as sales that take place within the store. [Tr.

305]. According to Mr. Robbin, this is an important distinction because convenience stores with gasoline stations only report their sales under code 20160 and not 20162; therefore, to get an accurate estimate of the nonprescription drug sales data for these specific stores, Mr. Robbin credibly stated that he first needs to look at the in-store sales for code 20160 to determine what proportion of those sales are connected to nonprescription drugs. [Tr. 305-06].

52. In preparing his assessment of nonprescription drug sales from convenience stores, Mr. Robbin stated that he also accessed a report prepared by IRI that outlines the top 200 over-the-counter nonprescription drug brands sold. [Tr. 312-13]. However, given that only one item listed was an ephedrine-based product (Primatene Mist), the report itself was only slightly helpful in Mr. Robbin's analysis. [Tr. 313]. Mr. Robbin further stated that the ephedrine products that are typically sold in convenience stores are not brands that are typically sold in non-convenience stores, which account for the majority of nonprescription drug sales. [Tr. 314]. Therefore, Mr. Robbin testified that it is necessary to look at the IRI data and impute the market share that the established brands represent to non-established brands, which are typically found in convenience stores. [Tr. 314].

53. Mr. Robbin credibly testified as to how the use of the "traditional" designation for the nonprescription drug market was established. [Tr. 316]. In looking at the 2002 census for NAICS

focusing on service code 20162 (nonprescription medicines), pharmacies and drug stores sold approximately $5.6 billion worth of nonprescription drugs, representing 43.5 percent of the total sales of nonprescription drugs. [Tr. 316; Govt. Exhibit 25A at 2]. Second to pharmacies and drug stores, supermarkets and other grocery stores' sales represented 21 percent of the market. [Tr. 317; Govt. Exhibit 25A at 2]. Adding in warehouse clubs and supercenters' sales, department stores' sales, and electronic shopping and mail-order houses' sales, these five categories, which Mr. Robbin considers the "major players" in the industry, total approximately 94 percent of the total market for nonprescription drugs. [Tr. 317; Govt. Exhibit 25A at 2].

54. Given these categories represent 94 percent of the market, Mr. Robbin stated that the term "traditional" is used to reflect the fact that consumers will typically purchase their nonprescription drugs from these entities. [Tr. 317].

55. Conversely, Mr. Robbin stated that convenience stores and gasoline stations with convenience stores represent approximately one percent of the market share of nonprescription drugs. [Tr. 318; Govt. Exhibit 25A at 2]. According to Mr. Robbin, consumers do not typically go to these stores to purchase their nonprescription drugs. [Tr. 318].

56. When asked if Mr. Robbin had an opinion as to why wholesalers would market the sale of List I chemicals to convenience stores, he responded

by stating that, given the low percentage of the overall market share convenience stores represent in nonprescription drug sales, it does not make sense to him why wholesalers would look to these stores to sell their items. [Tr. 319-20].

57. From the Census in 1997 to the Census in 2002, Mr. Robbin noted that there was a marginal change in the total percentage of sales of nonprescription drugs sold in convenience stores, which was not significant. [Tr. 321; Govt. Exhibit 25A at 3].

58. Nonprescription drugs represent a small amount of sales of convenience stores, specifically 1.6 percent. [Tr. 323-24; Govt. Exhibit 25A at 4]. Ninety-five percent of goods sold in convenience stores are characterized of other items including but not limited to cigarettes, beer and ale, candy, magazines and newspapers, deli items, and various food products. [Tr. 323; Govt. Exhibit 25A at 4]. The characteristic of a low percentage of overall sales of prescription drugs is also found in those convenience stores that have gasoline pumps. [Tr. 324-25; Govt. Exhibit 25A at 5].

59. Mr. Robbin credibly testified that a legitimate approach to validating one's findings, as he did for his CBS report, is to use independent data sources, such as MRI and NACS studies, that capture similar retail data. [Tr. 329-30, 333; Govt. Exhibit 23].

60. Mr. Robbin used the NACS report to compile a list that breaks down the various items found in convenience stores, noting total sales and

percentage of sales for the various items. [Tr. 336; Govt. Exhibit 25B].

61. Ephedrine guaifenesin is categorized under Code 30, Cough and Cold Remedies. [Tr. 338; Govt. Exhibit 25B at 1].

62. Using the NACS survey, Mr. Robbin calculated that the total sales for the Health and Beauty Care category to be approximately $1.72 million, which represents 1.2 percent of the convenience stores' sales. [Tr. 341; Govt. Exhibit 25B at 1]. Out of the different merchandise categories reflected in the NACS survey, the general Health and Beauty Care category ranked 14th out of a total of 15 categories. [Tr. 345; Govt. Exhibit 25B at 2].

63. When looking at the Health and Beauty Care – Cough and Cold Remedies subcategory, total sales for convenience stores for these products reflect.21 percent of the overall percentage of total sales. [Tr. 344; Govt. Exhibit 25B at 2]. Mr. Robbin testified that this small percentage figure reflects the fact that overall, convenience stores have very little shelf space for these particular products (about two or three feet) compared to a large pharmacy, for example, where there may be about 100 feet of shelf space. [Tr. 344].

64. Based on the NACS data, Mr. Robbin testified that his conclusion, which did not involve any detailed statistical analysis but could be deduced from a straightforward, logical observation, was that the convenience stores are not expected to sell much of nonprescription drugs,

including ephedrine-based products. [Tr. 347, 348; *see* Govt. Exhibits 25A and 25B].

65. Mr. Robbin credibly testified that, in his experience of frequenting convenience stores, he has not found "exotic" nonprescription-based products such as those you are also not likely to find in large stores. However, he knows that some convenience stores do sell large quantities of such items, given his work for DEA. [Tr. 347].

66. In his preparation of his report for DEA concerning CBS, Mr. Robbin stated that DEA provided him with invoices of CBS' sales of List I chemicals to its customers. [Tr. 352]. Mr. Robbin compiled the data into a table that reflected the different ephedrine-based products CBS sold to its customers. [Tr. 352; Govt. Exhibit 25C]. The invoices reflected the sale price at wholesale, and Mr. Robbin assessed the data to come to a conclusion as to the reasonableness of the average monthly retail sales vis-à-vis the expected amount of sales. [Tr. 353; Govt. Exhibit 25C].

67. Mr. Robbin also took the data, which represented sales to 42 stores over a three-month period, and separated out each transaction by date. [Tr. 355; Govt. Exhibit 25D]. Mr. Robbin explained his methodology in compiling Government Exhibit 25D from the CBS invoices he received. To accurately reflect the movement of the products (and ensure there was no bias against CBS), Mr. Robbin stated he first eliminated the pre-stock and restocking days. [Tr.

355-56]. Then, using the NACS report, he deduced the industry's average inventory turnover rate, which was 26 days. [Tr. 356; Govt. Exhibit 25D]. This was then used to compile the total number of selling days for CBS, and the total wholesale amount of sales was then divided by the total number of selling days to come up with an average daily sale. [Tr. 357; Govt. Exhibit 25D].

68. Additionally, Mr. Robbin computed the average number of days each convenience store replenished its ephedrine-based products, which Mr. Robbin stated is a good way to characterize the activity of the store. [Tr. 358-59; Govt. Exhibit 25D at 4]. These periods ranged from an average of 8.9 days to a total of 66 days. [Tr. 359; Govt. Exhibit 25D at 4].

69. Mr. Robbin also calculated the total dollar figure of sales starting with the first stocking day and then spreading it out equally over the whole period of selling days, which he had earlier calculated. [Tr. 362; Govt. Exhibit 25D at 7]. Mr. Robbin credibly stated that he did this in order to avoid bias against CBS. [Tr. 362-63].

70. Mr. Robbin then calculated the average monthly wholesale purchase price and then also calculated the average monthly retail sales by marking up the wholesale price by the gross margin, which was taken from the NACS report. [Tr. 364-65; Govt. Exhibit 25E].

71. Mr. Robbin testified that he had calculated the expected monthly sale of ephedrine asthma

medicines to be $14.39, which he stated was actually a high estimate for such items. [Tr. 367-68]. Comparing CBS' actual sales to the estimate sales, Mr. Robbin concluded that CBS' sales of ephedrine items were very high, with the smallest multiple being 5.2 times greater than the $14.39 expected sales figure. [Tr. 368; Govt. Exhibit 25E at 1].

72. In further assessing how far CBS's sales transactions were from the expected sales figure, Mr. Robbin then calculated a Z score using the standard deviation of $5.76.[48] [Tr. 370; Govt. Exhibit 25E]. By doing this, Mr. Robbin stated that then he could determine whether the actual sales were either far from the expected value (the implied average monthly sale), meaning the actual value was outside of the normal distribution range, or whether the actual values were close to the expected sales value (the mean in this calculation). [Tr. 370, 372].

73. Comparing the implied expected average monthly retail sales to the implied actual monthly retail sales of CBS's customers, Mr. Robbin compiled a Z score table that noted the probability of expecting an outcome greater

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[48] Based on testimony of Mr. Robbin, he commissioned the Census Bureau to calculate the standard deviation and construct the confidence intervals vis-à-vis the variables he was interested in. [Tr. 484]. The commissioned information was not appended to Mr. Robbin's report he prepared for CBS (Govt. Exhibit 25).

than the Z value. [Tr. 376-79; Govt. Exhibit 25E at 4]. According to Mr. Robbin, a Z calculation of 2.8 is the point where the probability of obtaining a Z score larger than 2.8 is quite unlikely. [Tr. 377-78; Govt. Exhibit 25E at 4]. As the Z score goes higher, the likelihood beomes even more inconceivable. [Tr. 378; Govt. Exhibit 25E at 4].

74. Mr. Robbin credibly testified that, in his estimation, none of the observed differences in CBS were insignificant, meaning that the observed sales did not happen by chance. [Tr. 379].

75. After compiling the data provided to him of CBS's sales to its customers, Mr. Robbin credibly testified that it was his opinion that the convenience stores to which CBS supplied ephedrine-based products sold in large excess of what one would expect in the normal stream of commerce. [Tr. 381; Govt. Exhibit 25 at 13].

76. Separate from CBS, when asked if he found there was any variance in the expected sales figures of ephedrine or pseudoephedrine-based products from region to region, Mr. Robbin stated that he has found very little variance in the analysis he has done. [Tr. 398].

77. While Mr. Robbin stated that his methodology has been peer reviewed in the past, his specific declaration and report pertaining to CBS was not peer reviewed. [Tr. 497-98].

78. When asked if he had compared his findings of the expected monthly sales of ephedrine and

pseudoephedrine with other data sources to confirm the legitimacy of his conclusions, Mr. Robbin stated that he had not. [Tr. 504].

79. Mr. Robbin did not take into account the treatment of colds, specifically the American Medical Association's estimate of pseudoephedrine consumption, given that the products CBS was distributing were ephedrine-based products. [Tr. 505, 507-08].

E. Mr. Robbin's Testimony of Novelty's Sales of Ephedrine Products

80. Mr. Robbin was provided sales invoices and summary data of Novelty's transactions with its customers concerning sales of ephedrine products. [Tr. 405; Govt. Exhibit 44].

81. Mr. Robbin testified that he felt Novelty's retail sales price of 24-count of ephedrine product of $9.99 or $10.99 was high, given that published price books show the price much lower. [Tr. 421]. Mr. Robbin stated that in the Thomson Medical Economics Red Book, it lists the price at approximately $6.00. [Tr. 421].

82. In assessing Novelty's summary data, which Mr. Robbin understood to reflect wholesale figures, Mr. Robbin stated that he was able to use the same gross margin markup that he used in his report for CBS, given that the two time periods observed in CBS and Novelty align together well. [Tr. 421-22, 525]. Mr. Robbin stated that the gross margin, as noted in

NACS, was for the industry at-large and is not unique only to one wholesaler. [Tr. 422].

83. After examining Novelty's data and summarizing the figures, Mr. Robbin concluded that Novelty's sales of ephedrine products were much larger than he would expect from a convenience store. [Tr. 427-28]. In looking at the two transactions in the month of May for Smoker Friendly (customer convenience store), the two add up to $383, which is approximately 20 times over the expected value, according to Mr. Robbin. [Tr. 427; Govt. Exhibit 44].

84. In assessing April sales for Smoker Friendly, Mr. Robbin stated that the total comes to approximately $1500 wholesale, which is about $2000 at retail. [Tr. 428; Govt. Exhibit 44]. Mr. Robbin stated that $2000 is a 100 times more than what he would expect to find in monthly sales transactions and his conclusion was that the retail customer was purchasing quantities of ephedrine in a much larger quantity than he would expect in the normal stream of commerce. [Tr. 428, 429].

85. In looking at the different List I products sold that are listed in the Novelty invoices, Mr. Robbin stated that it is his opinion that many of the products are ephedrine-based products and, therefore, he felt the expected value of $14.39 would be appropriate to use in his analysis of Novelty's transactions. [Tr. 442; Govt. Exhibit 38].

86. Looking at Novelty's sales transactions, Mr. Robbin stated that there were many transactions that exceeded what would be expected in the normal stream of commerce for ephedrine-based products, and it is unlikely that such transactions happened by chance. [Tr. 442; Govt. Exhibit 38].

87. Mr. Robbin stated that if Novelty's transactions included both pseudoephedrine and ephedrine products, then the expected value would rise to approximately $40 per month ($14.39 for ephedrine and $25 for pseudoephedrine products). [Tr. 443]. Applying this expected value to the transactions listed on the invoices, Mr. Robbin stated that one store purchased products in the neighborhood of $5000 in August, which is a hundred times more than what Mr. Robbin would expect. [Tr. 443; Govt. Exhibit 38].

88. Mr. Robbin credibly testified that he did not know the actual number of people that experience upper respiratory infections who visit convenience stores in the country. Also, he did not know the extent to which seasonal changes affect people experiencing cough and cold symptoms. [Tr. 455]. However, Mr. Robbin stated that he took into account seasonal patterns and allergies in coming up with the expected monthly sales value of $14.39, but these factors were not substantial enough to make any difference. [Tr. 456]. Mr. Robbin stated that he referenced the National Institutes of Health to get information on respiratory ailments, including asthma. [Tr. 459].

89. Mr. Robbin stated that a number of variables can influence the actual observations, like the convenience stores' hours, efficiency of management, and efforts targeted towards advertising and marketing. [Tr. 458]. He stated that these types of variables can affect the expected sales number, but added that they are considered only when determining an interval estimate and not when trying to calculate a specific number. [Tr. 458].

II. Testimony of Dr. Joanna M. Shepherd

A. *Educational and Professional Background of Dr. Shepherd*

90. Dr. Shepherd has a Ph.D. in Economics with a concentration in applied statistics (econometrics) and law and economics from Emory University. [Tr. 1597; Resp. Exhibit 58].

91. Dr. Shepherd is currently a Professor of Law at Emory Law School and teaches courses in Analytical Methods, Statistics for Lawyers, Torts, and Law and Economics. [Tr. 1597]. Dr. Shepherd also teaches courses in the Economics Department, including statistics. [Tr. 1597].

92. Prior to joining the faculty at Emory Law School, Dr. Shepherd was a professor at Clemson University, Emory University, and Georgia State University. [Tr. 1597]. She has taught courses in statistics, applied statistics (econometrics), and other economics courses to doctoral, graduate, undergraduate, and public policy students. [Tr. 1597].

93. Dr. Shepherd explained econometrics as applied statistics, where statistical findings are applied to real-word data. [Tr. 1598].

94. Dr. Shepherd has 19 publications, 11 of which are in peer-reviewed journals, fifteen are statistical papers, and of these 15 papers, 14 use Census Bureau data. [Tr. 1598, 1864; Resp. Exhibit 58 at 1-2]. Dr. Shepherd stated that the majority of her work is in applied statistics. [Tr. 1599].

95. Dr. Shepherd has testified as an expert on some of her statistical findings before the Congressional House Judiciary Committee and the National Academy of Sciences. [Tr. 1600-01; Resp. Exhibit 28 at 3; Resp. Exhibit 58 at 2].

96. Dr. Shepherd testified that she was also a consulting expert for the ACLU in a case involving methamphetamine and convenience stores approximately a year and a half ago. [Tr. 1601-02]. The case involved law enforcement trying to buy excess amounts of pseudoephedrine and ephedrine products and Dr. Shepherd was consulted and prepared reports concerning the likelihood that law enforcement would have indiscriminately gone into various convenience stores. [Tr. 1602, 1612-13]. The case was dismissed prior to Dr. Shepherd testifying. [Tr. 1612].

97. Dr. Shepherd has never been called as a witness in any federal, state, or administrative proceedings. [Tr. 1604].

B. Dr. Shepherd's Purpose as an Expert Witness for Novelty

98. Dr. Shepherd is being offered in the current proceedings as an expert in statistics and applied statistics; however, her report prepared for the Respondent states that she is an expert in theoretical and empirical analyses of legal changes. [Tr. 1614, 1616; ALJ Exhibit 14 at 3]. Dr. Shepherd testified that her proposed testimony is not within the field of theoretical and empirical analyses of legal changes; rather, her proposed testimony is based upon very simple computations to highlight fundamental problems with Mr. Robbin's calculations. [Tr. 1616-17].

99. Dr. Shepherd testified that she did not use simultaneous equation methods (technique where different variables are controlled for) in her work and preparation for Novelty. [Tr. 1619]. Rather, she stated that with her knowledge of applied statistics, she planned to illustrate the deficiencies of Mr. Robbin's methodology and show that different numbers should have been used, other than those used by Mr. Robbin. [Tr. 1620, 1629].

100. Her intent, as Dr. Shepherd testified, was not to offer her own findings, given that she did not do a separate multivariate statistical analysis, controlling for different factors; rather, her objective was to testify and show why Mr. Robbin should have used a multivariate statistical approach. [Tr. 1621; 1630-31].

101. Furthermore, Dr. Shepherd further explained that her purpose was not to testify concerning her report she prepared for Novelty. [Tr. 1634; *see* ALJ Exhibit 14 at 1-13].

C. *Dr. Shepherd's Position Concerning Mr. Robbin's Declaration and His Approach to Finding the Expected Sales Figure for Ephedrine*

102. Dr. Shepherd stated that Mr. Robbin erred in imputing the percentage of convenience stores that carry nonprescription drugs to convenience stores with gasoline stations without taking into account that the percentage could be different. [Tr. 1643-44; Govt. Exhibit 25A at 3].

103. Dr. Shepherd further notes that in comparing two tables Mr. Robbin compiled, he does not stay consistent with the figures he uses, pointing to vastly different overall totals of the number of convenience stores and different totals for the sales figures used in the tables. [Tr. 1644-47; Resp. Exhibit 25A at 2, 3]. Dr. Shepherd states that these discrepancies are noteworthy, particularly because if the larger figures as listed in Table D (25,702 convenience stores that carry nonprescription line) are used for Table C's compilation, convenience stores would rank much higher in the overall chart and move ahead of other retail establishments that Mr. Robbin considers part of the traditional market. [Tr. 1647, 1894; *see* Resp. Exhibit 25A at 1, 2, 3].

104. Dr. Shepherd stated that Mr. Robbin's imputation of the number of convenience stores (with and without gasoline stations) is accurately reflected in Table D, given his note summary; however, Table C, in Dr. Shepherd's estimation is not accurate. [Tr. 1852-53, 1934; Govt. Exhibit 25A at 3]. The figures imputed for Table C are not consistent with Mr. Robbin's note summary, in Dr. Shepherd's opinion. [Tr. 1853, 1894; Govt. Exhibit 25A at 2].

105. Mr. Robbin needed to impute the data reflected in both Table C and D in Government Exhibit 25A because the Economic Census does not specifically report on non-prescription items carried in convenience stores. [Tr. 1854; *see* Govt. Exhibit 25A at 2, 3].

106. Additionally, Dr. Shepherd testified that Mr. Robbin erred because two additional figures in Table D were not properly represented in Table C. [Tr. 1895-96]. Specifically, Table D noted that the total sales of nonprescription medicines in convenience stores with gasoline stations was approximately $33.3 billion and the total lines sales in the same category was approximately $238 million. [Tr. 1895-97; Govt. Exhibit 25A at 3]. However, in Table C, these figures change to approximately $3 billion and $32.5 million respectively. [Tr. 1895-97; Govt. Exhibit 25A at 2].

107. Dr. Shepherd testified as to the rate of response of the surveys upon which Mr. Robbin relied in his analysis. [Tr. 1649]. Dr. Shepherd stated that the response rate for the various

data sources was as follows: 37 percent for the Census Bureau; 15 percent for NACS; and .02 percent for MRI.[49] [Tr. 1649].

108. Dr. Shepherd further highlighted concerns of using data that obtains its information through self-reporting, stating that people or entities misreport things, which causes problems. [Tr. 1650]. For example, Dr. Shepherd stated that it was her understanding after speaking with Novelty executives that two of its largest customers, The Pantry and Circle K, which account for 55 percent of Novelty's ephedrine sales, self-report differently to these surveys and list their sales in this area as general merchandise instead of sales of cough and cold or sales of nonprescription medication.[50] [Tr. 1653-58].

109. Dr. Shepherd further testified that she had misgivings about Mr. Robbin's calculation of the expected monthly sales figure of $14.39. [Tr. 1659]. Based on her observations of the tables listed in Government Exhibit 25B and Mr. Robbin's declaration (Government Exhibit

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[49] It should be noted that with MRI, 50,000 consumers are surveyed, which Dr. Shepherd states reflects .02 percent of consumers in the country.

[50] Dr. Shepherd credibly testified that, though some of Novelty's customers misreported their sales of ephedrine, it was not relevant whether or not they properly reported the sales of other over-the-counter prescription drugs. [Tr. 1864-65]. Furthermore, until she is informed to the contrary, she approaches her analysis that entities do not make mistakes in terms of their reporting. [Tr. 1865].

25), Dr. Shepherd went through her understanding of how Mr. Robbin arrived at the expected sales value. [Tr. 1662-66; Govt. Exhibit 25B; ALJ Exhibit 15 at 1]. While she could attribute two of the figures Mr. Robbin used to the data or to his testimony, she was not able to ascertain where Mr. Robbin arrived at the eight percent figure to represent the total amount of ephedrine-based product sales, but assumed that it came from either the MRI or WI data. [Tr. 1665, 1673-74].

110. While she disputed Mr. Robbin imputing the eight percent figure to convenience stores, she credibly testified that she had no reason to believe this figure was inaccurate vis-à-vis pharmacies, department stores, drug stores, and grocery stores, although she did not see the actual tables. [Tr. 1878].

111. In assessing Mr. Robbin's eight percent figure was too low, Dr. Shepherd considered Novelty's data, the difference of store size of convenience stores versus pharmacies and like entities, and the large variety of products the larger entities carry versus convenience stores. [Tr. 1881, 1888-89]. Taking these factors into account, Dr. Shepherd stated that the portion of nonprescription drug sales containing ephedrine as a percentage of sales would rise. [Tr. 1881, 1889].

112. Additionally, she highlighted the government's assertion that some pharmacies and like entities that DEA investigators visited, within the area where Novelty's customers are located, do not carry ephedrine products. [Tr.

1889]. Tying this into the national estimate of sales of pharmacies and like entities, Dr. Shepherd concluded that this would bias the estimated market sales of ephedrine downward. [Tr. 1889].

113. Moreover, Dr. Shepherd notes the problems with the total number of stores she believes Mr. Robbin uses in the denominator, which is 140,000 stores. [Tr. 1666]. She stresses that in Mr. Robbin's report, Mr. Robbin states that only about 40,000 total convenience stores (with and without gasoline stations) carry non-prescription drugs.[51] [Tr. 1666-67; Govt. Exhibit 25A at 3]. Therefore, Dr. Shepherd states by using the total number of convenience stores as the denominator, rather than the total number of convenience stores that actually carry non-prescription drugs, Mr. Robbin is using a denominator that is not reflective of the actual observations he is totaling in his numerator.

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[51] Dr. Shepherd stated that she does not disagree with Mr. Robbin's assertion that there were approximately 40,000 convenience stores with and without gasoline stations, based on the data from the Census Bureau. [Tr. 1736, 1860-61]. She further testified that she didn't have reason to believe the 40,000 figure was misleading because, while some convenience stores might miscategorize the reporting of the sale of some of their products (here, ephedrine products), they do still report the sale of the products. [Tr. 1860-61].

[Tr. 1667-68, 1918; *see* Govt. Exhibit 25A at 3; *see* ALJ Exhibit 15[52] at 1].

114. Using the total number of convenience stores that carry nonprescription drugs as the denominator and keeping all other numbers equal, Dr. Shepherd showed that the expected monthly sales rises to $50. [Tr. 1668-69; *see* ALJ Exhibit 15 at 1].[53]

115. Dr. Shepherd then took her calculations a step further and noted that 12 states either prohibit the sale of ephedrine products or have very strict regulations. [Tr. 1669, 1918]. Based on the NACS data, Dr. Shepherd stated that approximately 23 percent of those convenience stores that carry nonprescription drugs are located in these twelve states. [Tr. 1669, 1918]. Factoring this into the equation, Dr. Shepherd then showed how the denominator can be reduced to 31,000, representing the maximum number of convenience stores carrying ephedrine products.[54] [Tr. 1670, 1920; ALJ Exhibit

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[52] ALJ Exhibit 15 is a reproduction that both parties agreed to of Dr. Shepherd's calculations, which she demonstrated during her testimony.

[53] Dr. Shepherd stated that she took the approximate 40,000 value as indicated in Table D instead of the smaller total number of convenience stores selling nonprescription drugs as indicated in Table C (approximately 22,000), in order to come to a more conservative result. [Tr. 1668].

[54] In reducing the number of stores from 40,000 down to 31,000, to account for those states that restrict the sale of ephedrine in convenience stores, Dr. Shepherd did not believe that she was double counting because her understanding was that

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15 at 1]. Using this lower number and keeping all other values constant, Dr. Shepherd shows that the expected monthly sales then increases to $65.

116. In Dr. Shepherd's opinion, Mr. Robbin's use of the 140,000 figure, which is the total number of convenience stores in the industry, was the most fundamental error. [Tr. 1911-12, 1916-17]. Given that Mr. Robbin added up sales data for the approximate 31,000 stores (which reflects the total number of convenience stores that carry ephedrine-based products), Dr. Shepherd stated that this was the number he should have used in the denominator when he was computing the expected monthly sales value. [Tr. 1911-12].

117. Approximately, one-third of all of Novelty's customers purchase ephedrine products. [Tr. 1921-22]. However, in Dr. Shepherd's hypotheticals, she did not impute this percentage to the convenience store industry at-large for her denominator because had she done so, she stated that she would have gotten a figure of 47,000. [Tr. 1922]. Given that only 40,000 convenience stores sell nonprescription drugs, this would

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these states only restrict the sale of ephedrine and not nonprescription drugs in totality. [Tr. 1738]. Also, the 31,000 number is based on the most recent economic census (2002), reduced based on the most recent state laws in 2007; however, Dr. Shepherd stated that the number of convenience stores do not vary that much over this period of time (5 years), so there is no reason to question the reliability of the 31,000 figure. [Tr. 1900].

have been an improper denominator to use in her calculation.[55] [Tr. 1922-23].

118. Dr. Shepherd then focused on the figures used in the numerator. [Tr. 1670]. First, Dr. Shepherd took issue with the fact that Mr. Robbin imputed the eight percent figure denoting the total amount of sales of ephedrine products to all retail store establishments. [Tr. 1675]. By doing so, Dr. Shepherd stated that Mr. Robbin engaged in aggregation bias because he assumed that the eight percent figure applied accurately across the board for all retail stores.[56] [Tr. 1675]. Dr. Shepherd noted that given the variance in store size among pharmacies, supermarkets and convenience stores, it is incorrect to impute a national average number for all retail stores to a portion of stores in the retail store industry (convenience stores). [Tr. 1674-76]. With smaller store area, Dr. Shepherd stated that convenience stores would not have the same amount of shelf space for nonprescription drug products as larger stores;

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[55] If the one-third figure was imputed to the industry at-large, however, Dr. Shepherd stated that this would not affect the expected sales figure greatly. [Tr. 1925-27]. Further, she stated that the Z-scores she calculated for Novelty using its data (Respondent Exhibit 27A) would not affect the standard deviation in any way; it's not related. [Tr. 1927-28].

[56] Though Dr. Shepherd could not testify with certainty from where Mr. Robbin obtained the eight percent figure, she presupposes that this figure was obtained from either MRI or IRI data, which she states represents national average numbers for all retail establishments. [Tr. 1674-76].

however, one would expect then that ephedrine-based products would make up a larger share of the nonprescription drug products that are sold in convenience stores. [Tr. 1676].

119. Focusing strictly on Novelty sales, Dr. Shepherd illustrated why the eight percent figure was faulty in her opinion and is an example of aggregation bias on the part of Mr. Robbin.[57] [Tr. 1675, 1677]. Using Novelty's assertions that 60 percent[58] of the sales revenue of cough and cold products its customers sell come from ephedrine products instead of the eight percent figure used by Mr. Robbin, the monthly expected sales figure rises to $470.[59] [Tr. 1676-77, 1884; ALJ Exhibit 15 at 1].

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[57] In determining that Mr. Robbin's eight percent figure was too small, Dr. Shepherd did not take into account the retail price of other cough and cold remedies. [Tr. 1885-86].

[58] Dr. Shepherd stated that the 60 percent figure is based upon all of the cough and cold products that Novelty's customers sell and represents the percentage of sales revenue attributed to products containing ephedrine. [Tr. 1907-08]. While Dr. Shepherd stated she believed Novelty's data represented the actual retail price (versus suggested retail price), she was not sure and stated that is a detail that one would want to know; however, she did not think that a few dollars difference would make a significant change in the outcome. [Tr. 1913-14].

[59] In Dr. Shepherd's testimony, she states that the 60 percent figure is noted in an affidavit by Mark Bledsoe of Novelty; however, I note that this affidavit was not admitted into evidence. [Tr. 1676, 1776; *see* Resp. Exhibit 27 at 3]. Further, I note Dr. Shepherd's use of Novelty's figures is not to produce what the expected monthly sales should be, but rather to show that using the eight percent figure is not accurate for all retail

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120. Though items in convenience stores are generally priced higher, Dr. Shepherd stated that the higher markup of ephedrine products is not relevant to the 60 percent figure, because this figure is based upon an estimate of the total percentage of sales of cough and cold products that contain ephedrine. [Tr. 1909]. However, she further noted that, if ephedrine products are generally more expensive in convenience stores than other entities, this gives further impetus to her position that the eight percent figure Mr. Robbin uses is too low. [Tr. 1909-10].

121. Dr. Shepherd further commented on her disagreement with Mr. Robbin's use of the $292 million in industry sales.[60] [Tr. 1682]. Focusing on the possibility that convenience stores might misreport their data in the surveys, similar to Novelty's two largest customers, Dr. Shepherd stressed that using the $292 million figure is inaccurate, given that one could expect some convenience stores to report their

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stores, specifically convenience stores. [*See* Tr. 1677]. Dr. Shepherd acknowledged that the 60 percent figure she uses is from Novelty, which has an interest in the outcome of the calculations, and is, therefore, biased. [Tr. 1780-81]. Furthermore, she had no reason to believe convenience stores misreport their products in this area until Novelty made her aware of this issue. [Tr. 1876]. Dr. Shepherd credibly testified that she is not confident as to what the actual percentage should be; however, she did state with confidence that the eight percent figure is too low based on statistical standards on aggregation bias. [Tr. 1780-81].

[60] This figure is from 2006, and Dr. Shepherd noted it is close in terms of the period for which Novelty provided its sales data (2007). [Tr. 1900; 1907].

ephedrine products in categories other than cough and cold products. [Tr. 1683, 1886]. To emphasize her point, Dr. Shepherd did another calculation where she multiplied the $292 million and the 60 percent of ephedrine-based sales by two (accounting for the possibility that up to half of convenience stores might misreport) to show that the monthly expected sales value ends up increasing to $940.[61] [Tr. 1684, 1874; ALJ Exhibit 15 at 1].

122. In imputing the misreporting of Novelty's customers to the convenience industry at-large, Dr. Shepherd stated that though this assumption does not yield an accurate final conclusion, it is more helpful of an assumption to make rather than to impute figures of pharmacies and like entities to the convenience store industry. [Tr. 1879-80, 1886].

123. In her assumption that stores might misreport their data, where they specifically report the sale of nonprescription drugs under "general merchandise," she did state that she thought about the possibility of the reverse outcome,

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[61] In assessing Dr. Shepherd's calculations, I note that she assumes about half of the convenience stores misreport their data in her hypothetical; however, there is no evidence to suggest this, other than the statement that Novelty's two largest customers misreport their data. Dr. Shepherd stated that she did not confirm the misreporting of ephedrine products with the customers nor did she further inquire with Novelty on this issue. [Tr. 1862]. However, I do find it noteworthy that her calculation exemplifies the importance of controlling for various factors, including misreporting.

whereby stores might misreport items under nonprescription drug category, which do not belong there. [Tr. 1875-76]. However, while taking this factor into account, she credibly testified that there was no reason for her to believe that retailers would categorize nonprescription drug items in this category, but that the reverse is likely because it is easier for entities to report their sales under "general merchandise," rather than to break down their sales into the individual categories. [Tr. 1875-76].

124. Dr. Shepherd stated that in terms of the two equations that yields a $470 and $940 monthly expected sales figure, she is starting from the conclusion that the figures Mr. Robbin uses are too small, although she credibly states that she is not aware how small these figures are, and further notes that she is using Novelty data to highlight her problems with Mr. Robbin's methodology. [Tr. 1880-81].

125. In assuming Mr. Robbin's eight percent figure is accurate, and taking into account Dr. Shepherd's assumption that up to half of the convenience store industry misreports its data, the monthly expected sales figure is $129. [Tr. 1887-88, 1892-93; ALJ Exhibit 14 at 4].

126. In the various hypothetical calculations Dr. Shepherd presented, she stressed that the results show that in trying to come up with a cumulative number to represent the industry of convenience stores, one needs to ensure that

there is no unnecessary aggregation bias built in. [Tr. 1685; ALJ Exhibit 15 at 1].

127. Dr. Shepherd also stated that the inherent problem in coming up with one cumulative number to represent all stores is that the stores that comprise the industry vary as well; therefore, a multivariate approach is necessary to account for these differences. [Tr. 1686]. Factors such as store hours, store location, store size, advertising expenditures, and management practices, should be taken into account in Dr. Shepherd's opinion. [Tr. 1686-88].

128. Furthermore, focusing in on ephedrine products alone, Dr. Shepherd underscored the need to also account for seasonal and environmental conditions, noting that asthma-related conditions are more prominent at certain times of year in certain regions of the country, as discussed by the National Institute of Allergy and Infectious Diseases.[62] [Tr. 1688-89].

129. By taking into account the different variables that Dr. Shepherd outlined, she stated that one would then come up with more accurate predicted sales figures for the different types of convenience stores within the industry. [Tr.

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[62] I note that Dr. Shepherd is not a medical doctor; however, I find that her testimony on the importance of taking into account seasonal and environmental factors when determining ephedrine sales is directly applicable to her testimony on ensuring that various variables are accounted for in statistical methodology.

1686-90]. Then, the actual observed sales figures can be compared to these predicted sales figures, which yields a more precise analysis. [Tr. 1689-90].

130. Dr. Shepherd stated that Mr. Robbin discussed multivariate statistics in his declaration prepared for CBS; however, he did not actually use a multivariate statistical analysis, as he also stated during his testimony. [Tr. 1686-87, 1824-25].

131. Dr. Shepherd testified that she did not take into account FDA-approved uses of ephedrine products into her calculation. [Tr. 1808]. However, she did credibly testify that understanding the usage of products is important when calculating expected sales, depending upon the analysis being done. [Tr. 1809, 1811]. For example, in a new analysis, such information would likely be important; however, in preparing a response to another's report, such information would only be necessary if it was considered in the report that is being critiqued. [Tr. 1811].

132. Dr. Shepherd credibly stated that she did not take into account the number of occurrences of conditions that ephedrine is used to treat because her purpose in testifying was to directly refute Mr. Robbin's testimony. [Tr. 1812].

133. Were she to do her own analysis, Dr. Shepherd stated that she would do a multiple regression analysis, taking into account factors such as the prevalence of those conditions which ephedrine is used to treat. [Tr. 1812]. This latter

factor is important, Dr. Shepherd stated, when one is doing an analysis focusing on demand; however, it is not a relevant factor when focusing on the supply. [Tr. 1813].

134. The National Heart, Lung, and Blood Institute's 2007 Report (NHLB Report) did not list ephedrine as a treatment for asthma.

135. Though Dr. Shepherd is not a medical expert, she stated that she was surprised that ephedrine was not listed in the NHLB Report, considering the testimony she heard during the proceedings discussed ephedrine as a treatment for asthma. [Tr. 1816, 1840].

136. However, Dr. Shepherd stated she did not believe the NHLB Report itself was applicable to her testimony concerning Mr. Robbin's methodology, even when she factored in Novelty's assertion that 60 percent of its customers' sales of cough and cold products contain ephedrine into her analysis, because the focus of her testimony and Mr. Robbin's methodology focused on supply and not demand. [Tr. 1814-15].

137. A total of 62,025 convenience stores (with and without gasoline stations) carried items within the Drug, Health and Beauty Care line (Code 20160) in 2002. [Tr. 1847-48; Govt. Exhibit 25A at 3]. A total of approximately 124,000 convenience stores were accounted for in the 2002 Economic Census. [Tr. 1848-49; Govt. Exhibit 25A at 1]. Therefore, approximately half of the convenience stores in the 2002 Economic Census carried items belonging to Code 20160. [Tr. 1849].

138. After the passage of state laws that curtailed the sale of ephedrine products, the effect was that the sale of ephedrine products in convenience stores in those states greatly diminished or "dried up." [Tr. 1868].

139. Dr. Shepherd did not consider the reduction of the number of convenience stores carrying ephedrine products within the last 18 months in her analysis because she directly refuted the methodology of Mr. Robbin; however, she did credibly testify that were this detail to be included in the analysis, the total number of convenience stores carrying ephedrine products she uses as a denominator (31,000) would be reduced, as well as the expected amount of retail sales. [Tr. 1868; *see* ALJ Exhibit 15 at 1].

140. Dr. Shepherd was not aware of the term "gray market" being used in a technical manner; however, she was aware of the term being used to refer to an illegitimate market. [Tr. 1931]. Furthermore, Dr. Shepherd stated she was not aware of either the terms "traditional" or "nontraditional" being used within her field of study. [Tr. 1932].

D. Z-Score Analysis

141. As Mr. Robbin also testified, Dr. Shepherd explained that a Z-score analysis looks at actual numbers that are different from the expected value and then assesses whether the actual numbers (observed values) are different

enough to such a degree where one would conclude that the observed values are not random or did not happen by chance. [Tr. 1690-91].

142. To calculate the Z-score, the actual sales are subtracted from the expected sales, and then this number is divided by the standard deviation. [Tr. 1704; ALJ Exhibit 15 at 2]. If a Z-score is greater than plus two or less than negative two, this shows that the observed value is statistically different from the expected value. [Tr. 1704-05].

143. Dr. Shepherd explained that in looking at a normal distribution curve and calculating the Z-score, there is a range that lies directly under the curve (two-tail/standard deviation range from the expected value on either side); any observed values falling inside within the shaded parameters are not considered different enough from the expected value.[63] [Tr. 1699, 1702; ALJ Exhibit 15 at 2]. Typically, 2.5 percent of the observations are expected to occur by chance, but in terms of looking at

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[63] I note that in discussing Z-scores and if actual values fall within or outside the accepted range and applying that specifically to the proceedings at hand, an actual value falling outside the acceptable range, meaning the observed value did not happen by chance, would indicate the diversion of ephedrine, according to the DEA. However, Dr. Shepherd states that finding an observed value statistically different than the expected value, which indicates randomness, is not outright indicative of illegitimate sales; there could be legitimate reasons to explain the randomness but one would need to rely upon additional information to explain it. [Tr. 1700, 1703].

sales, the 2.5 percent is so unlikely that one would conclude that those observations lying within this 2.5 percent "tail" are statistically different. [Tr. 1939].

144. Dr. Shepherd did not agree with the manner in which Mr. Robbin calculated the Z-score in his report for CBS. [Tr. 1691]. The $14.39 expected sales figure, as Dr. Shepherd previously noted, contains aggregation bias and so the Z-score analysis performed for the various customers in CBS is not an accurate reflection of the randomness of the actual sales. [Tr. 1691]. By using an expected value that is lower than it should be, Dr. Shepherd stressed that the Z-scores are falsely biased higher than they should be. [Tr. 1705].

145. Dr. Shepherd also did not agree with Mr. Robbin's Z-score assessment of Novelty's sales, where he noted that the sales figures he was given for six stores were far over what he would expect to be sold by a convenience store in a month. [Tr. 1691, 1695-97; *see* Govt. Exhibit 38, 44].

146. To showcase her reservations about Mr. Robbin's Z-score analysis, Dr. Shepherd computed the Z-scores for all of Novelty's customers that carry ephedrine products (3,629 convenience stores) from November 2007 to January 2008.[64]

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[64] Out of all the stores that sold ephedrine products as noted in the data, Dr. Shepherd stated that she believed all the stores to be selling ephedrine products in January 2008. [Tr. 1937]. However, she was not aware if all the stores represented

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[Tr. 1692, 1698, 1719, 1903-1905]; Resp. Exhibit 27A]. The sales figures for Novelty were supplied to her by the Respondent and she believed the sales figures to be calculated at retail, not wholesale.[65] [Tr. 1728-29; Govt. Exhibit 97A].

147. Dr. Shepherd used the three different monthly expected sales values, which she calculated in her demonstration [*see* ALJ Exhibit 15 at 1, 2], to compute the Z-scores for Novelty's customers.[66] Focusing on the most conservative monthly sales estimate used ($65/month), Dr. Shepherd noted that approximately 365 of Novelty's customers had Z-scores greater than two. [Tr. 1720, 1904; Resp. Exhibit 27A]. Focusing on the $470 monthly sales figure, an estimated 195 of Novelty's customers had Z-scores greater than two. [Tr. 1720-21, 1904; Resp. Exhibit 27A]. Finally, in using the largest monthly sales estimate of $941/month, roughly 100 of Novelty's customers had Z-scores greater than

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in Novelty's data sold in each month of the three-month period reflected in Respondent Exhibit 27A. [Tr. 1938].

[65] In looking at information for Customer CKO5, in both Respondent Exhibit 27A and Government Exhibit 97A, I note that the average monthly sales figure that Dr. Shepherd computed for this customer was based on the retail sales price, as noted in the "MSRP Net Retail" column in Government Exhibit 97A. Therefore, I conclude that the expected monthly sales values she computed for each store from November-January 2007 is based on retail numbers supplied to her by Novelty.

[66] The standard deviation of the average monthly sales, which is computed with ease in Excel, was 600. [Tr. 1904].

two.[67] [Tr. 1721, 1904; Resp. Exhibit 27A]. Dr. Shepherd stressed that those stores with Z-scores greater than two showed that they were statistically different; however, the reason for the difference was not readily explainable. [Tr. 1721].

148. In focusing on store CKO44, Dr. Shepherd reached a probability conclusion that over the three month period, the Z-score indicated that the sales of ephedrine for this store did not happen by chance. [Tr. 1906; Govt. Exhibit 27A at 1].

149. Dr. Shepherd noted that courts will typically use a Z-score of two or three as a threshold of statistical significance and commented on the United States Supreme Court Case, *Castaneda v. Partida*, where this was discussed. [Tr. 1904-05].

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[67] Dr. Shepherd states that this is 2.7 percent of Novelty's customers and compares this to the 2.5 percent expected level of randomness (at the tail end) in a Z-score analysis, noting that the two percentages are very close. [Tr. 1721]. While the number of Novelty's customers' with Z-scores over two is reduced with the expected monthly sales figures that Dr. Shepherd uses, I note that her Z-score analysis is not indicative of Novelty's customers' true Z-scores, given that these expected sales figures are general hypothetical estimates computed to highlight the potential errors in Mr. Robbin's methodology. However, I do recognize the variance that will occur in a Z-score analysis when a different expected sales figure is used in the analysis, further underscoring the importance of having an expected value that is as accurate as possible.

150. Dr. Shepherd noted that, generally, all the stores' Z-scores were within the expected range; however, she highlighted store BPM55, whose Z-scores were much higher than the other stores. [Tr. 1698; Resp. Exhibit 27A].

151. Dr. Shepherd explained that store BPM55 is Novelty's top seller and is not representative of Novelty's other retail customers. [Tr. 1698, 1721-22]. Dr. Shepherd stated that without doing a multivariate statistical analysis, one cannot control for factors that might account for the difference in the total sales.[68] [Tr. 1698-99]. Furthermore, it would be incorrect to take an outlier like store BPM55, which is not representative of all the stores, and then draw a conclusion of these stores based upon the outlier itself. [Tr. 1722].

152. When asked if her Z-score analysis would change if the retail prices were actually higher than what was provided to her by Novelty, Dr. Shepherd credibly testified that a difference of $4.00 in the retail price, for example, would not significantly change the majority of the Z-scores for each of the stores that she calculated because of the large standard deviation. [Tr. 1730-31].

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[68] While BPM55 might not be representative of Novelty's other customers, this is not the focus. An individual store might not be representative of the whole, but the focus is on how to account for the high level of sales. Dr. Shepherd does not provide an explanation of the high level of sales for BPM55, other than to state that a multivariate statistical analysis would be appropriate to determine this.

153. A large retail sales number does not automatically demand a large standard deviation. [Tr. 1934]. The standard deviation represents the variation among stores; here the stores that Novelty serves. [Tr. 1935]. However, the number of total stores does affect the standard deviation, given that the average deviation is divided by the total number of stores; however, a difference of approximately 20 in the total number of stores would not significantly affect the standard deviation that is computed.[69] [Tr. 1935-36, 1937].

154. If the calculation in ALJ Exhibit 15 on page 4 were to be accurate in terms of the numbers used, then the monthly expected sales of $129 would fall somewhere closer to the first Z-score column that Dr. Shepherd calculated (using the $65 expected monthly sales). [Tr. 1939-42; ALJ Exhibit 15 at 4; Resp. Exhibit 27A]. In this case, roughly eight percent of Novelty's customers would have Z-scores in the upper tail of the distribution curve. [Tr. 1942].

155. Dr. Shepherd credibly testified that a Z-score analysis is a valid analysis when only one variable is being considered and there is no need to account for other variables. [Tr. 1702-03,

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[69] I note that in Respondent Exhibit 27A, there are 39 stores that have a negative retail sales figure. [Resp. Exhibit 27A]. Dr. Shepherd took this into account and separately computed the Z-scores without these stores and stated that the change was minimal. [Tr. 1935-36]. She did include those stores that had a retail sales average of zero because these would have to be included. [Tr. 1936].

1902]. With one variable in question, the Z score allows for statistical conclusions to be drawn. [Tr. 1902].

156. Dr. Shepherd credibly testified that she felt the utility of the Z score analysis is limited to the proceedings at hand because it does not account for multiple variables. [Tr. 1902].

E. Dr. Shepherd's Position on the Economic Census and NACS Data

157. Dr. Shepherd did not disagree with Mr. Robbin's using both the Economic Census and the NACS data in his analysis. [Tr. 1732]. Dr. Shepherd further agreed that in terms of a representative sample, a 37 percent response rate for a survey the size of the Economic Census is respectable and considered a good rate. [Tr. 1731-32].

158. Additionally, the Census accounts for those entities that do not respond and weight this issue accordingly into its tabulated data. [Tr. 1876-77].

159. However, Dr. Shepherd credibly stated that she did not think there was a way for the Census to account for the percentage of the general merchandise that actually is nonprescription drugs. [Tr. 1877].

160. Similarly, a 15 percent response rate for the NACS survey is considered respectable; however, Dr. Shepherd stated that the survey was not representative of the industry as a whole. [Tr. 1733; *see* Govt. Exhibit 23 at 6]. For example,

65 percent of the stores that responded to the survey are chains that have over 500 stores; however, these chains represent only 13 percent of the industry as a whole. [Tr. 1733]. However, she did acknowledge that the survey, similar to the Economic Census, corrects for these discrepancies. [Tr. 1733].

161. Though the NACS survey has a high response rate from chain stores, these types of stores are reflective of Novelty's customer base as a whole. [Tr. 1733-34].

162. Both the Economic Census and the NACS survey have the retail data of the retail outlets. [Tr. 1915]. When the Census and NACS ask about the sales of nonprescription drugs, this question deals with retail sales. [Tr. 1915].

F. Dr. Shepherd's March 12, 2008 Report Prepared for Novelty

163. Dr. Shepherd prepared a report for the Respondent titled, "The Economic Impact of Revoking Novelty, Inc.'s Registration to Sell Ephedrine and Pseudoephedrine to Convenience Stores," dated March 12, 2008. [Tr. 1739; ALJ Exhibit 14].

164. Dr. Shepherd testified that she focused her report on pseudoephedrine, given that all past

DEA proceedings published in the Federal Register, which discussed Mr. Robbin's findings, focused on pseudoephdrine.[70] [Tr. 1818, 1830].

165. Her purpose in preparing the report was not to conduct her own study as to the legitimate market sales of pseudoephedrine (or ephedrine), but to directly critique Mr. Robbin's methodology. [Tr. 1835]. Were she to have conducted her own study on the legitimate demand for pseudoephedrine (and ephedrine), she stated that she would do a multiple regression analysis, taking into account different factors. [Tr. 1835-36].

166. Dr. Shepherd consulted the Economic Census, specifically summaries of the Census that describes the process by which the information was gathered, and also looked at state-by-state data. [Tr. 1864].

167. Dr. Shepherd testified that in terms of market demand, she discussed this in regards to pseudoephedrine but not ephedrine. [Tr. 1823-24, 1834]. She performed an analysis of Mr. Robbin's pseudoephedrine conclusions; however, she did not do the same for ephedrine in her report because she was not aware of the methodology he used for ephedrine. [Tr. 1830, 1834, 1837; ALJ Exhibit 14].

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[70] In Dr. Shepherd's report, she discusses both pseudoephedrine and ephedrine. [Tr. 1819-22; ALJ Exhibit 14]. Dr. Shepherd further notes her misgivings about Mr. Robbin's assumption of the percentage of cough and cold products containing ephedrine. [Tr. 1820-21; ALJ Exhibit 14 at 3].

168. Dr. Shepherd testified that she was not aware of the methodology Mr. Robbin used in terms of his ephedrine-based study in his declaration; it was not until Mr. Robbin's testimony that she realized he used supply factors to establish the legitimate demand, rather than demand factors like he did for his pseudoephedrine analysis. [Tr. 1824].

169. In preparing her report, Dr. Shepherd accessed the tables listed in Mr. Robbin's Declaration [Govt. Exhibit 25], DEA's website, the National Institutes of Health, and the American Medical Association, all resources that are generally accepted by experts within her field. [Tr. 1741; *see* ALJ Exhibit 14].

170. Dr. Shepherd had access to Mr. Robbin's declaration, which dealt primarily with ephedrine, when she prepared the March 12, 2008 report. [Tr. 1819].

171. Dr. Shepherd had previously prepared a report for Novelty, dated September 5, 2007, and to the best of her knowledge, cited to the sources she used in the report. [Tr. 1743-46].

172. Both her March 12, 2008 report and her September 5, 2008 report for Novelty were reviewed by another economist with a doctorate degree. But based on the technical definition of "peer review," which is a very precise process based on anonymity, neither report was "peer reviewed". [Tr. 1804-05].

173. Within Dr. Shepherd's March 12, 2008 report for Novelty, she cites to a summary fact sheet

prepared by the National Institute of Allergy and Infectious Diseases (NIAID). [Tr. 1748-49; Govt. Exhibit 92; ALJ Exhibit 14]. Within the summary, NIAID notes that over a year's time, people within the United States will suffer one billion colds. [Tr. 1798-99; Govt. Exhibit 92 at 1].

174. In Dr. Shepherd's March 12, 2008 report, she states that there are one billion cases of colds and asthma a year, and she testified that while the NIAID summary only discusses colds, NIH has estimated that there are 30 million asthma sufferers in the United States. [Tr. 1799; Govt. Exhibit 92 at 1]. She further stated that because the report was prepared to directly rebut Mr. Robbin's assertions about pseudoephedrine sales, she did not think it necessary to cite to the NIH report concerning numbers relating to asthma. [Tr. 1802-03].

175. Dr. Shepherd acknowledged that ephedrine is not used to treat colds and that her report is inconsistent on this issue; however, she credibly stated that in order to avoid double counting and to be as conservative as possible in her calculation, she only used the one billion figure and did not add to that the 30 million estimated asthma sufferers in the United States.[71] [Tr. 1799-1802].

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[71] Dr. Shepherd's lack of specificity in her report, where she does not specify that pseudoephedrine is used to treat colds and includes the discussion of ephedrine-based remedies, is not accurate. Furthermore, I note that the National Heart, Lung, and

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176. Statistical experts are mindful that changes in the law will have an impact on economic forces, and, depending on what is being analyzed, might or might not take this fact into account when analyzing data. [Tr. 1752-53].

177. Dr. Shepherd stated that she believed she took into account the Combat Methamphetamine Epidemic Act (CMEA) in her analysis of Mr. Robbin's methodology because she factors in the twelve states that restrict the sale of ephedrine in her estimated total of 31,000 convenience stores, and this total number is dependent upon the CMEA. [Tr. 1754, 1756-57]. While Mr. Robbin's methodology does not take into account this fact in Dr. Shepherd's estimation, Dr. Shepherd stated that it is relevant because it highlights the incorrect denominator that Mr. Robbin uses in his calculation, with the denominator being the total number of convenience stores. [Tr. 1758]. More specifically, Dr. Shepherd credibly testified that the focus is more on the individual states laws; however,

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Blood Institute in its 2007 report stated that more than 22 million persons in the United States suffer from asthma. [Govt. Exhibit 93]. While I concur with Dr. Shepherd in her statement that only using the one billion number is more conservative than using one billion and thirty million, I note that the one billion number denotes the number of cases of colds, while the number of asthma sufferers does not show the number of cases of asthma that individuals will encounter. This is another inaccuracy. Though, the number of asthmas-related [sic] cases would likely be higher than 22 million, this is an assumption not supported by the evidence in the record.

the CMEA was the impetus to the enactment of these laws. [Tr. 1757-59].

178. Dr. Shepherd cited to the Consumer Healthcare Products Association (CHPA) in her March 12, 2008 report; however, the report itself does not indicate that convenience stores are an "essential means for reaching an estimated 1 billion Americans each year who suffer from colds and debilitating asthma and obtain relief from OTC ephedrine remedies," as Dr. Shepherd notes in the report. [Tr. 1763-67; Govt. Exhibit 91]. Rather, Dr. Shepherd stated that she used the CHPA report in compilation with other resources to come to this conclusion.[72] [Tr. 1767].

179. In her March 12, 2008 report, Dr. Shepherd took issue with Mr. Robbin's use of the term "nontraditional" to define the convenience store market of List I chemicals because in her estimation, there was no technical basis for his assertion. [Tr. 1761-62; 1772-73]. Furthermore, with his faulty methodology, Dr. Shepherd claims that he has ranked convenience stores with gasoline stations lower than other retail industries that he terms "traditional." [Tr. 1772].

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[72] Dr. Shepherd was questioned regarding the "1 billion Americans" statement, but explained this number represented the total number of ailments experienced by Americans. [Tr. 1769-70]. However, I note that the CHPA report itself misstates this fact, where it states that "[e]ach year, an estimated one billion Americans suffer from colds, according to the latest data from the National Institutes of Health." [Govt. Exhibit 91 at 2].

180. To emphasize her position about Mr. Robbin's labeling of convenience stores as a non-traditional market, Dr. Shepherd used numbers straight from the Economic Census and showed that the percentage of total sales contributed by ephedrine products in the overall percentage of sales of nonprescription medicines was .038 percent. [Tr. 1897-98; ALJ Exhibit 14 at 4]. The .038 percent figure is actually higher in comparison to other entities that Mr. Robbin labels as part of the "traditional market," in Dr. Shepherd's opinion. [Tr. 1898].

181. However, Dr. Shepherd also cited to the CHPA, which states the following: "Unfortunately, there are illegitimate producers making products using these ingredients. These illegitimate producers are not members of CHPA and often sell their products at nontraditional outlets. They sell their products in large quantities – far larger than could be reasonably used by the average consumer – and most likely are not packaged in federally mandated blister packs." [Tr. 1771; Govt. Exhibit 91 at 2]. Not having any further information upon which CHPA makes its assertion, Dr. Shepherd testified that she could not comment on her acceptance or non-acceptance of CHPA's use of the term "nontraditional." [Tr. 1173-74].

182. Dr. Shepherd was not aware that Novelty's suppliers, specifically Kirk, Lehigh, AAA and DMD, are not members of CHPA. [Tr. 1869]. She did not take into account any supply side information for Novelty to this end. [Tr. 1869].

183. Dr. Shepherd testified that she used a January 16, 2002 Slone Survey, which reported on the medication use in the ambulatory adult population, to estimate the sales of pseudoephedrine. [Tr. 1783; Govt. Exhibit 90]. Dr. Shepherd credibly stated that it would be standard for those in the statistical field to rely upon reports, such as the Slone Survey, and added that it was proper in the instant case because Mr. Robbin had previously estimated the legitimate sales level of pseudoephedrine in previous proceedings and the survey was directly on point with this topic. [Tr. 1784, 1786].

184. The Slone Survey lists by percentage the 40 most commonly used prescription and over-the-counter drugs, broken down by gender and age. [Tr. 1785; Govt. Exhibit 90 at 4]. Though ephedrine was considered in the survey, it is not on this list; however, pseudoephedrine hydrochloride is ranked fourth. [Tr. 1785, 1797; Govt. Exhibit 90 at 4].

185. Dr. Shepherd did not believe that the absence of ephedrine on the Slone survey list of top 40 drugs was in any way significant to her findings, based on how she approached her calculations. [Tr. 1794].

186. In terms of Dr. Shepherd's methodology in writing her March 12, 2008 report, she credibly testified that she resourced other reports, which included the conditions and occurrences of those conditions that pseudoephedrine is

used to treat, because the numbers she found directly contradicted those in Mr. Robbin's report. [Tr. 1811-12].

187. Dr. Shepherd stated in her report that it makes sense for consumers dealing with asthma to stockpile ephedrine products instead of going to the store each time they have an episode.[73] [Tr. 1842-43, 1892; ALJ Exhibit 14].

188. Dr. Shepherd stated that it was not relevant, in her estimation, to include data reflecting the decrease in ephedrine purchases of Novelty's customers following the enactment of the CMEA, because her report focused on the legitimate market of pseudoephedrine sales. [Tr. 1866]. This is different than her September 7, 2007 report, where she did include this information; however, she stated that she did so because that report focused on this very issue. [Tr. 1866-67].

III. Post-Hearing Interrogatories and Rebuttal of Dr. Shepherd and Mr. Robbin

A. *Interrogatories Propounded Upon Dr. Shepherd*

189. In Dr. Shepherd's opinion, Novelty's customers selling ephedrine, which totals 3,269 stores,

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[73] There is no specific evidence to support this statement in the report; however, Dr. Shepherd stated that there is an economic theory that discusses the stockpiling of different items. How this theory relates directly to the proceedings at hand is unknown, however.

are not representative of the 146,249 convenience stores in the country. [Govt. Exhibit 98B at 1]. Most of Novelty's customers (98 percent) are chain stores; however, chain stores only represent approximately 35 percent of the industry at-large. [Govt. Exhibit 98B at 1]. Therefore, Novelty's customer base is representative of the chain store sector of the industry, according to Dr. Shepherd, but not the industry at-large. [Govt. Exhibit 98B at 1].

190. Given that Novelty's customers are chain stores for the most part, Dr. Shepherd stated that it is less likely then that these stores are selling more than the expected legitimate sales of ephedrine items. [Govt. Exhibit 98B at 1].

191. The Z-score analysis Dr. Shepherd prepared is focused on Novelty's stores and she compares the average monthly sales of Novelty's customers with the three theoretical expected monthly sales she calculated. [Govt. Exhibit 98B at 1]. Given the theoretical monthly sales takes into account chain and independent stores, this automatically biases the average monthly sales downward. [Govt. Exhibit 98B at 1]. The effect of considering these variables yields an expected monthly sales average that is higher than what one would expect for independent stores, and is lower than what one would expect for chain stores. Chain stores, as used here, are typically larger in size, have longer hours, carry more products, and are located in high traffic consumer areas. [Govt. Exhibit 98B at 1].

192. To correct for this, Dr. Shepherd stated that a multivariate approach is required; this takes into account the different types of convenience stores that exist within the industry and their different characteristics. [Govt. Exhibit 98B at 1-2]. This is essential when assessing legitimate sales. [Govt. Exhibit 98B at 1-2].

193. In Dr. Shepherd's Z-score analysis, she added up each store's sales for a period of 12 weeks and then divided by three to get an average monthly sale for each store for the period of November 2007 through January 2008. [Govt. Exhibit 98B at 2]. Were she to have added up the daily sales for each store and then divided by the total number of days (84) and then multiplied that by 30 to get a monthly sales average, she noted that the number of stores with a Z-score of two or larger rises slightly. [Govt. Exhibit 98B at 2]. The result does not change Dr. Shepherd's earlier conclusion that very few of Novelty's customers sell more ephedrine than what would be expected. [Govt. Exhibit 98B at 3].

194. Additionally, Dr. Shepherd reiterated that about 2.5 percent of the stores observed are expected to be outside the expected range when analyzing a typical two-tailed Z-score; however, this does not mean that diversion is occurring. Rather, Dr. Shepherd states that a multivariate analysis needs to be done, taking into account factors such as store size and hours, variety of items, and location, in order to ascertain the reason behind the higher-than-expected sales. [Govt. Exhibit 98B at 3].

195. In looking at the monthly sales averages for all of Novelty's customers, there were 39 stores that had negative sales averages and 13 that had a zero sales average, and Dr. Shepherd stated that these stores should or should not be factored into the analysis, depending upon the reason for these sales averages. [Govt. Exhibit 98B at 3].

196. Assuming that the negative and zero sales averages were for returns and no sales, Dr. Shepherd stated that it would be necessary to include these figures into the analysis because they are an accurate representation of the overall traffic of the ephedrine products. [Govt. Exhibit 98B at 3].

197. Conversely, assuming that the negative and zero sales averages were due to coding mistakes or because there were actually no sales during the three-month period, then Dr. Shepherd stated that these stores should not be included in the overall analysis. [Govt. Exhibit 98B at 3]. However, omitting these stores from the overall sample size has minimal effect on the outcome. [Govt. Exhibit 98B at 3-4].

B. Mr. Robbin's Rebuttal Declaration

198. Mr. Robbin stated that Dr. Shepherd's approach is flawed because she derives an expected monthly sales average using only Novelty data for its 3,629 stores that it serves and then asserts that this is representative of the

convenience store industry at-large.[74] [Govt. Exhibit 99 at 2]. According to Mr. Robbin, weights must be applied to the individual observations in order to normalize the distribution. [Govt. Exhibit 99 at 2].

199. To emphasize his point, Mr. Robbin discusses the "bias of prior selection," whereby he notes the problems that arise when a sample of observations are taken from the same population. [Govt. Exhibit 99 at 2]. Mr. Robbin explains that by approaching the study in this manner, a certain segment of the population is then overrepresented. [Govt. Exhibit 99 at 2]. A random sample is needed to make legitimate statistical inferences. [Govt. Exhibit 99 at 2].

200. Dr. Shepherd's approach, in Mr. Robbin's opinion, ensures the outcome that is desired; namely, that the most excessive sales of Novelty's customers appear "normal." [Govt. Exhibit 99 at 2]. The effect is a biased conclusion, according to Mr. Robbin. [Govt. Exhibit 99 at 3]. Additionally, he notes that Dr. Shepherd's analysis is skewered [sic] because she is using selecting data, rather than using objective, scientific data, like the Economic Census and other trade surveys. [Govt. Exhibit 99 at 4].

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[74] While I understand Mr. Robbin's assertion, at no point did Dr. Shepherd represent Novelty's data as the norm for the entire convenience store industry. Rather, as I understand her testimony to show, her purpose was to highlight her misgivings as to Mr. Robbin's monthly expected sales value and she utilized Novelty data to show her perceived discrepancies in Mr. Robbin's methodology.

201. Mr. Robbin further disputes Dr. Shepherd's claim that chain stores have larger-sized convenience stores, and, therefore, will have more space for more product selection. [Govt. Exhibit 99 at 3-4]. Mr. Robbin references the NACS report, which shows that individual stores or companies with up to ten stores actually have more store space than chain companies, with over 500 stores. [Govt. Exhibit 99 at 4; Govt. Exhibit 23 at 54].

202. Mr. Robbin further criticizes Dr. Shepherd's imputation to the industry at-large that 60 percent of cough and cold remedies are ephedrine-based products and asserts that this is another example of biased analysis. [Govt. Exhibit 99 at 4]. According to Mr. Robbin, ephedrine product sales are nominal in pharmacies, supermarkets and like entities, further supporting his position that her 60 percent figure is inaccurate. [Govt. Exhibit 99 at 4].

203. Mr. Robbin is in disagreement over the computation of Dr. Shepherd's monthly average sales for Novelty customers for the 12 week period prior to Novelty's suspension. [Govt. Exhibit 99 at 4]. Mr. Robbin states that instead of simply adding up the sales and then dividing by three to get a monthly average, Dr. Shepherd should have first produced an annual average by dividing by 12 to get a weekly average and then multiplying by 52 to get an annual average and then finally dividing by 12 to get the monthly average. [Govt. Exhibit 99 at 4]. Mr. Robbin states that Dr. Shepherd is "stacking the deck" with her approach and the result

is an average that is lower by almost eight percent. [Govt. Exhibit 99 at 5]. Furthermore, he states that when Dr. Shepherd takes the daily average first and then multiplies by 30 to get a monthly average, she is underestimating the number of days in a year by 1.4 percent and, again, overestimates the expected value.[75] [Govt. Exhibit 99 at 5].

204. Mr. Robbin states that Dr. Shepherd's use of the term "aggregation bias" is misplaced, and believes she is actually referring to "under-specification," which means that outside factors have not been taken into account to explain the differences of the observed sales. [Govt. Exhibit 99 at 5]. Terminology aside, Mr. Robbin does not believe that there are any outside variables that would produce an expected value that is significantly different than the expected value he calculated.[76] [Govt. Exhibit

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[75] I understand that Dr. Shepherd's method accounts for only 360 days out of the year; however, it is not clear, based upon Mr. Robbin's assertion, the significance of this overestimation. Furthermore, it is unclear to me how this relates to the discussion of the expected value, given that his discussion is focused upon the average monthly sales for Novelty stores. In reviewing Dr. Shepherd's surrebuttal declaration, I find that this difference is negligible and would not produce varied results. [*See* Resp. Exhibit 59 at 4-5].

[76] Mr. Robbin states that store size is the most significant variable that influences retail sales; however, he further notes that, though 60 percent of the variance in store sales can be explained by this factor, only 3.6 percent of convenience stores have twice the average size of all year-round convenience stores. [Govt. Exhibit 99 at 5].

99 at 5-6]. Applying this to Novelty specifically, Mr. Robbin asserts that considering outside factors, such as store size and hours, would not alter the outcome, given that some of Novelty's stores sell 50 times over the expected value.[77] [Govt. Exhibit 99 at 6].

205. Mr. Robbin states that Dr. Shepherd erred in her interpretation of his approach in computing the monthly expected sales value of $14.39 and explained the way he calculated the figure. [Govt. Exhibit 99 at 6-7]. First, Mr. Robbin determined the cough and cold average monthly sales per store for 2006. [Govt. Exhibit 99 at 7]. Mr. Robbin notes that the Economic Census indicates 50 percent of convenience stores carry items in Code 20160 and 31.5 percent carry items in Code 20162. [Govt. Exhibit 99 at 7]. These percentages were then applied to the NACS survey, which highlights revenue by product categories. [Govt. Exhibit 99 at 7]. Second, Mr. Robbin then determined the average monthly sales of ephedrine tablet products for 2006 by referencing MRI data that highlights

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[77] I note that Mr. Robbin is using the monthly expected value that he computed – $14.39 – in his analysis of Novelty sales. Additionally, while Mr. Robbin asserts that outside variables are "drowned out" by the large variance of Novelty's actual sales from the expected value, it is not clear to me that taking these factors into account in the approach from the front end would not alter the outcome. Based on Mr. Robbin's explanation, it seems that he is approaching the issue of using outside variables at the tail end of the analysis, while Dr. Shepherd asserts that outside variables need to be taken into account from the beginning in the calculation.

asthma-related remedies by form (e.g. tablet, mist) and determined the estimate of $14.78. [Govt. Exhibit 99 at 8]. Mr. Robbin then looked up the wholesale prices of the top brand ephedrine products, specifically Bronkaid and Primatene, and then determined the retail sales price of the products by using the gross margin factor noted in the NACS survey. [Govt. Exhibit 99 at 8]. Finally, Mr. Robbin then took the average retail price of the two brands and then multiplied it by two to come to an expected value of $14.39. [Govt. Exhibit 99 at 8-9].

C. Surrebuttal Declaration of Dr. Shepherd

206. Dr. Shepherd rebutted Mr. Robbin's assertion that she calculated the monthly expected sales value using Novelty data; rather, the monthly expected sales figure was derived using the computation Dr. Shepherd believed Mr. Robbin used and she maintained this formula throughout her analysis.[78] [Resp. Exhibit 59 at 1-2].

207. Dr. Shepherd defends her Z-score analysis by noting that the only way to do the analysis is to calculate the standard deviation for Novelty's stores because that is the only data at her disposal. [Resp. Exhibit 59 at 2]. The Z-score, Dr. Shepherd reiterates, assesses the difference

[78] Having listened to Dr. Shepherd testify and going through her calculations, I do note that she did not derive the monthly sales figure using Novelty data pertaining to its 3,629 stores.

between the observed average monthly ephedrine sales and the expected average monthly ephedrine sales value weighed against the standard deviation. [Resp. Exhibit 59 at 2]. There is no other way to compute the real standard deviation, given the existing data that both parties use, according to Dr. Shepherd. [Resp. Exhibit 59 at 2]. Furthermore, Dr. Shepherd states that, given the large sample size of Novelty stores, it would be reasonable to infer that the variation of sales among Novelty's stores are similar to the variation of sales of other stores.[79] [Resp. Exhibit 59 at 3].

208. Dr. Shepherd notes her misgivings about the standard deviation Mr. Robbin uses, which is $5.76. To get an accurate standard deviation, Dr. Shepherd notes that Mr. Robbin would need to consider the individual sales information for each convenience store in the country, information which he does not have. [Resp. Exhibit 59 at 2]. Additionally, two of the sources Mr. Robbin uses in his calculation do not contain standard deviation information. [Resp. Exhibit 59 at 2-3].

209. Dr. Shepherd refutes Mr. Robbin's criticism of her assertion that chain stores have larger sales than non-chain stores and notes that the NACS survey supports her position. In the

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[79] I note here that Novelty's customer base, as Novelty has presented during the proceedings, reflects chain stores. So, the variation then, if proper to infer to other stores, would only be accurate as to other chain stores of similar makeup.

NACS survey, stores with over 51 stores in the chain had sales over $1 million compared to non-chain stores of 10 stores or fewer, which had average sales of $880,000.[80] [Resp. Exhibit 59 at 3; Govt. Exhibit 23 at 44-46]. By focusing his criticism of Dr. Shepherd's statement that store size is a variable that could affect sales among stores, she states that he is avoiding the reality that chain stores typically have higher sales than independent stores. [Resp. Exhibit 59 at 3]. Moreover, Dr. Shepherd stresses that Mr. Robbin is making a gross inference by concluding that the inverse relationship of store size to the amount of stores within a chain necessarily results in smaller overall sales in these stores versus independent stores. [Resp. Exhibit 59 at 3, 5-6].

210. Dr. Shepherd defends her usage of the 60 percent figure from Novelty, which represents the amount of sales attributable to ephedrine products out of the entire cough and cold category of products, noting that her information is specific to convenience stores and compares ephedrine to other cough and cold products. [Resp. Exhibit 59 at 4]. Responding to Mr. Robbin's criticism, Dr. Shepherd states that Mr. Robbin's reliance upon the fact that ephedrine tablets are not part of the top 200 sellers

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[80] Looking at the table in the NACS survey, I do find that chains with a large number of convenience stores do have overall sales that are larger than independent convenience stores or chains with a smaller number of stores. [Govt. Exhibit 23 at 44-46].

of nonprescription drugs is misguided because the data comes from drugstore, supermarkets and like entities and not from convenience stores. Furthermore, the information pertains to all nonprescription drugs and is not limited to the cough and cold category of products. [Resp. Exhibit 59 at 4].

211. Dr. Shepherd notes that Mr. Robbin biases the estimate of legitimate sales of ephedrine downward when he takes into account information relating to the convenience store market as a whole, which is composed of about 35 percent chain convenience stores. [Resp. Exhibit 59 at 6]. Novelty's customers represent 98 percent of chain convenience stores and so imputing the information as Mr. Robbin does, forces the average sales downward and is lower than what chain stores actually experience. [Resp. Exhibit 59 at 6-7].

212. Dr. Shepherd reiterated her approach towards calculating the expected monthly sales value of ephedrine products for convenience stores, which is to perform a multivariate regression analysis, where differences among the convenience stores are controlled for, including but not limited to customer base, store size, store hours, geographical location, and environmental conditions. [Resp. Exhibit 59 at 7].

213. Dr. Shepherd assesses the formula Mr. Robbin uses to calculate the expected monthly sales value for ephedrine products, noting that it is similar to the formula she used during her

testimony. [Resp. Exhibit 59 at 8-9]. Her layout of Mr. Robbin's formula is the following:

$$\frac{\$292{,}000{,}000}{71{,}565} * .08 * \frac{1}{12} * .52$$

Dr. Shepherd notes the $292 million figure is the total sales of cough and cold products for the entire convenience store industry, as noted in the NACS survey. [Resp. Exhibit 59 at 8]. The 71,565 figure is the number of convenience stores carrying the product Code 20160 line, as noted in the Economic Census. [Resp. Exhibit 59 at 8]. The .08 figure represents the percentage of sales of cough and cold products that are ephedrine. [Resp. Exhibit 59 at 8]. The .52 number represents the percentage of ephedrine users that use ephedrine tablets instead of other ephedrine-type products, like inhalers. [Resp. Exhibit 59 at 9].

214. Dr. Shepherd states that the 71,565 figure is incorrect to use because it does not take into account that not all convenience stores that carry the product Code 20160 line also carry ephedrine products. [Resp. Exhibit 59 at 10]. According to the NACS and Census data, only about 45,000 stores carry nonprescription drugs. [Resp. Exhibit 59 at 10]. At a maximum, Mr. Robbin should be using the 45,000 number in the denominator. [Resp. Exhibit 59 at 10]. At a maximum, Mr. Robbin should be using the 45,000 number in the denominator. [Resp. Exhibit 59 at 10].

215. Dr. Shepherd goes on to show why the 45,000 number is still too high, stressing that 12 states restrict the sale of ephedrine products. [Resp. Exhibit 59 at 10]. Approximately 23 percent of convenience stores are located in these states, which brings the total number of stores to be used in the denominator down to 34,709. [Resp. Exhibit 59 at 10]. Using this new figure in the denominator, Dr. Shepherd shows that the monthly sales average rises to approximately $29.

216. Dr. Shepherd disagrees with the .08 figure Mr. Robbin uses to reflect the percentage of sales of cough and cold products that are ephedrine. [Resp. Exhibit 59 at 11]. Dr. Shepherd notes that Mr. Robbin calculates the eight percent figure from the MRI survey; however, she states that there is not information contained within this survey that pertains to ephedrine. [Resp. Exhibit 59 at 11]. Additionally, the MRI survey does not contain any information that indicates whether an individual purchased either an asthma-related remedy or a cough and cold remedy from a convenience store. [Resp. Exhibit 59 at 11]. The questions the survey poses do not provide accurate information to the percentage that Mr. Robbin uses. [Resp. Exhibit 59 at 11]. In Dr. Shepherd's estimation, Mr. Robbin comes to the eight percent figure by cross-tabulation, where he makes an assumption of the percentage of sales of cough and cold products that are ephedrine based upon (1) how many people bought any nonprescription drug in a convenience store and (2) how many

individuals used an asthma remedy in general. [Resp. Exhibit 59 at 11].

217. Instead of using the eight percent figure that Mr. Robbin uses, Dr. Shepherd uses the 60 percent figure she received from Novelty in the formula [FOF217], which yields a monthly expected sales average of $218.73, 15 times larger than Mr. Robbin's expected sales value. [Resp. Exhibit 59 at 12].

218. Dr. Shepherd disagrees with the .52 figure Mr. Robbin uses and states that the MRI survey does not contain information on ephedrine. [Resp. Exhibit 59 at 12]. So, Dr. Shepherd concludes that Mr. Robbin imputed the percentage of people who use tablets for cold, sinus and allergy remedies to those people that use ephedrine tablets for their ailments, instead of ephedrine-based inhalers. [Resp. Exhibit 59 at 12]. She further critiques Mr. Robbin's approach, noting that there is no evidence that any of Novelty's customers sell inhalers. [Resp. Exhibit 59 at 12].

219. Substituting the eight percent figure for the 60 percent figure from Novelty, and taking out the .52 figure (which Dr. Shepherd states is unnecessary because the 60 percent figure measures the percentage of sales of ephedrine tablet products within the cough and cold remedy class), Dr. Shepherd calculates the monthly expected sales value to be $420.64, which is 29 times larger than Mr. Robbin's estimate. [Resp. Exhibit 59 at 12-13].

220. Finally, Dr. Shepherd focuses on the overall total sales of cough and cold products within the industry. [Resp. Exhibit 59 at 13]. Dr. Shepherd notes that using this figure presupposes that no convenience stores misreport their data. [Resp. Exhibit 59 at 13]. However, she affirms that two of Novelty's largest customers and other customers, which total 50 percent of Novelty's sales, misreport their sales of cough and cold products or nonprescription drug products as "general merchandise." [Resp. Exhibit 59 at 13]. Imputing this misreporting occurrence to the convenience industry at-large,[81] the total sales figure rises to $584 million ($292 million multiplied by two), and plugging this figure into the formula, the monthly expected sales figure rises to $841.28, which is 58 times greater than Mr. Robbin's estimate.

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on May 21, 2008, caused a copy of the foregoing to be hand delivered to Brian Bayly, Esq. and D. Linden Barber, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, DC 20537, and a copy to be hand delivered to Respondent's Counsel, Jonathan W.

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[81] I note here that Dr. Shepherd is not asserting that up to half of all convenience stores misreport their data in this area, given that there is no direct evidence to this effect. Rather, the purpose is to show the result if fifty percent of all convenience stores did misreport their data.

Emord, Esq., Emord & Associates, P.C., 1050 Seventeenth Street, N.W., Suite 600, Washington, D.C. 20036.

/s/ Carlene R. Thomas
Carlene R. Thomas
Secretary to
The Honorable Gail A. Randall

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 08-1296 **September Term, 2008**
FILED ON: JUNE 22, 2009

NOVELTY, INC.,

PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION, ET AL.,

RESPONDENTS

On Petition for Review of an Order
of the Drug Enforcement Administration

Before: HENDERSON, TATEL and BROWN, *Circuit Judges*.

ORDER

(Filed Jun. 22, 2009)

It is ORDERED, on the court's own motion, that by 4:00 p.m. on July 1, 2009, the parties show cause why the separate statements in this case should not be unsealed. The responses may not exceed 10 pages.

FOR THE COURT:
Mark J. Langer, Clerk

By /s/ Michael C. McGrail
Michael C. McGrail
Deputy Clerk

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 08-1296 **September Term 2008**

DEA-73FR52689

Filed On: June 22, 2009 [1186604]

Novelty, Inc.,

Petitioner

v.

Drug Enforcement Administration, et al.,

Respondents

ORDER

It is **ORDERED**, on the court's own motion, that the Clerk withhold issuance of the mandate herein until seven days after disposition of any timely petition for rehearing or petition for rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. Rule 41. This instruction to the Clerk is without prejudice to the right of any party to move for expedited issuance of the mandate for good cause shown.

FOR THE COURT:
Mark J. Langer, Clerk

By /s/ Michael C. McGrail
Michael C. McGrail
Deputy Clerk

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 08-1296 **September Term 2008**

DEA-73FR52689

Filed On: July 28, 2009

Novelty, Inc.,

Petitioner

v.

Drug Enforcement Administration, et al.,

Respondents

BEFORE: Henderson, Tatel, and Brown,* Circuit Judges

ORDER

Upon consideration of petitioner's petition for panel rehearing filed on July 13, 2009, it is

ORDERED that the petition be denied.

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* Circuit Judge Brown would grant the petition for rehearing.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

By /s/ _____
Michael C. McGrail
Deputy Clerk

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 08-1296 **September Term 2008**

DEA-73FR52689

Filed On: July 28, 2009

Novelty, Inc.,

Petitioner

v.

Drug Enforcement Administration, et al.,

Respondents

BEFORE: Sentelle, Chief Judge, and Ginsburg, Henderson, Rogers, Tatel, Garland,* Brown, Griffith, and Kavanaugh, Circuit Judges

ORDER

Upon consideration of petitioner's petition for rehearing en banc, and the absence of a request by any member of the court for a vote, it is

ORDERED that the petition be denied.

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* Circuit Judge Garland did not participate in this matter.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

By /s/ _____
Michael C. McGrail
Deputy Clerk

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

NOVELTY, INC., Plaintiff, v. KAREN TANDY, Administrator, U.S. Drug Enforcement Administration, and MICHAEL MUKASEY, Attorney General of the United States, each in their respective official capacities, Defendants.	)	CASE NO. 1:04-cv-1502-DFH-TAB

ENTRY ON CROSS MOTIONS
FOR SUMMARY JUDGMENT

Plaintiff Novelty, Inc. sells items such as sunglasses, lighters, key chains, and plush toys to gas stations and convenience stores. Novelty also sells certain over-the-counter pharmaceuticals that contain List I chemicals under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* Those chemicals are regulated by the Drug Enforcement Administration ("DEA"). On May 5, 2004, Dan Raber, the Diversion Group Supervisor for the DEA's Indianapolis office, sent a letter to Novelty and all other Indiana companies that are registered to manufacture or distribute List I chemicals. Raber's letter presented a

series of instructions regarding storage of List I chemicals in delivery vehicles.

Novelty believes the new instructions will impose new and onerous restrictions on its ability to distribute its products, and it sued the Administrator of the DEA and the Attorney General for a declaratory judgment that the instructions announced in the Raber letter are invalid.[1] In issuing the instructions in the Raber letter, DEA did not use the notice-and-comment procedures required by the Administrative Procedure Act, 5 U.S.C. § 553, for "legislative" rules, as distinct from "interpretive" rules. The parties have filed cross-motions for summary judgment. As explained below, the court finds that the rules announced in the Raber letter were interpretive and not legislative, so that notice-and-comment procedures were not required. The court therefore grants the defendants' motion and denies the plaintiff's motion.

Summary Judgment Standard

The purpose of summary judgment is to "pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Summary judgment must

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[1] Attorney General Mukasey is substituted as a defendant in this action pursuant to Rule 25(d)(1) of the Federal Rules of Civil Procedure.

be granted "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The motion should be granted so long as no rational fact finder could return a verdict in favor of the non-moving party. See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A court's ruling on a motion for summary judgment is akin to that on a motion for a directed verdict. The question for the court in both is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251-52. Only genuine disputes over material facts can prevent a grant of summary judgment. *Id.* at 247-48. A fact is material if it might affect the outcome of the suit under the governing law, and a dispute about a material fact is genuine only if the evidence would allow a reasonable jury to return a verdict for the non-moving party. *Id.* at 248.

The fact that both sides have filed motions for summary judgment does not alter the applicable standard; the court must consider each motion independently and must deny both motions if there is a genuine issue of material fact. *E.g., Heublein, Inc. v. United States,* 996 F.2d 1455, 1461 (2d Cir. 1993); *Harms v. Laboratory Corp. of America,* 155 F. Supp. 2d 891, 905-06 (N.D. Ill. 2001). In considering cross-motions for summary judgment, the court must consider the evidence through two lenses. When

considering Novelty's motion for summary judgment, the court must give the defendants the benefit of all conflicts in the evidence and the benefit of all reasonable inferences that might be drawn from the evidence in their favor. When considering the defendants' motion for summary judgment, the roles are reversed. Because the court is granting defendants' motion, the court sets forth the evidence viewed in the light reasonably most favorable to plaintiff Novelty.

Facts for Summary Judgment

The Controlled Substances Act ("CSA") classifies as List I chemicals specified chemicals that are used to manufacture controlled substances. 21 U.S.C. § 802(34). Any person wishing to manufacture or distribute a List I chemical must obtain a registration from the DEA, which must be renewed annually. 21 U.S.C. § 822(a)(1). Novelty sells and distributes a variety of items such as sunglasses, key chains, and plush toys. It also sells and distributes over-the-counter pharmaceuticals, including the decongestant ephedrine hydrochloride, which contains a List I chemical.

Novelty has established distribution practices for all of its products, including products containing List I chemicals. Novelty sales representatives order items that are shipped by transport trucks from the Greenfield, Indiana warehouse to "satellite transshipment points" or storage units. Bledsoe Dep.

22-23. Each sales representative picks up products from an assigned storage unit and distributes the products to customers. Sales representatives are sometimes unable to complete their routes in one day and may need to stay overnight somewhere before resuming their delivery routes.

Novelty obtained a DEA Certificate of Registration that permits it to distribute List I chemicals. As part of the registration process, a diversion investigator from the DEA's Indianapolis office conducted an investigation of Novelty in 1998. Kuzma Dep. 51. The DEA was aware that Novelty planned to use satellite storage locations and that sales representatives would not always be able to complete their routes in one day. *Id.* at 51-52. The DEA conducted investigations of Novelty in 2002-2003 and in 2007 so that Novelty could renew its registration, and the DEA continued to be aware of Novelty's distribution practices. At no time during the pre-registration or subsequent investigations did the DEA inform Novelty that its practices violated the federal regulations regarding distribution of List I chemicals. *Id.* at 54.

On July 30, 2004, the DEA published a notice of proposed rule-making in the Federal Register that proposed increasing the security requirements for storage of pseudoephedrine, ephedrine, and phenylpropanolamine ("PPA"). 69 Fed. Reg. 45,616 (July 30, 2004), Def. Ex. F. Though this notice was published after the Raber letters [sic] was written, it provides important context for the DEA's actions regarding the

distribution of List I chemicals. The notice explained that pseudoephedrine, ephedrine, and PPA can be used to manufacture methamphetamine and amphetamine illegally. These drugs pose a danger to the public based on the effects they have on users' health, the pollution they cause, and the connection between their use and other criminal activity. *Id.* at 45,619. As the DEA increased controls on the sale of over-the-counter products containing these chemicals, the DEA observed an increase in the number of thefts of products containing these chemicals from manufacturers and distributors. *Id.* at 45,617. The DEA provided lists of reported thefts of large quantities of these chemicals. *Id.* at 45,618-19. The DEA proposed that security be increased in areas where these chemicals are stored, the details of which DEA provided in the notice. *Id.* at 45,619-20.

Before issuing that July 30, 2004 notice of proposed rule-making, the DEA had tried to clarify its policies on the distribution of List I chemicals under the existing regulations. The first evidence of a "clarification" of the regulations regarding the distribution of List I chemicals that has been presented to the court is a December 23, 2003 letter sent by Marsha Jones, the DEA's Diversion Program Manager for the Kansas City District Office, to all registrants in the Kansas City region. Pl. Ex. H. Jones wrote that the purpose of her letter was to remind all List I chemical distributors that the CSA and its implementing regulations require all registrants to maintain separate registrations for

separate locations from which they distribute List I chemicals. *Id.*, citing 21 U.S.C. § 822(e), and 21 C.F.R. § 1309.23. Jones wrote:

> It has come to our attention that some registrants are handling List I chemical products (including over-the-counter ephedrine and pseudoephedrine items) by storing them at, and distributing them from, satellite locations, such as commercial storage units, personal residences and/or delivery vehicles. Any storage at, and distribution from, a location other than the registered location (including the use of delivery vehicles for overnight storage) is a violation of federal law.

Id. Jones then reminded registrants that they faced possible imprisonment and/or fines if they distributed List I chemicals from an unregistered location. *Id.*, citing 21 U.S.C. § 843(d)(1).

That position obviously troubled the industry. On January 26, 2004, John Mudri, the compliance officer for the American Council on Regulatory Compliance, asked the DEA to provide an "official interpretation" of the Jones letter. Pl. Ex. G. Mudri wrote:

> Our members understand that a delivery vehicle, commercial storage units etc. cannot be used as storage for future distribution, but many of our members have salesmen that travel for as much as a week at a time to make deliveries, without returning to the registered location for additional supplies. Many of these salesmen must stay in motels

> during the week and storage remains in these secured vehicles while parked.

Mudri requested that DEA clarify its policy on whether sales representatives could store the chemicals in their trucks while they stayed overnight on the road.

Patricia Good, the chief of the DEA's Liaison and Policy section, assigned the task of responding to Mudri's letter to Andy McFaul, unit chief of the Regulatory section. McFaul drafted a response letter with the help of Cathy Brooks, staff coordinator in the DEA's Regulatory Drafting section. Good Dep. 84-85. Brooks and McFaul met with Scott Collier and Mark Rubbins from the Chemical section and Brian Bayly from the Office of the Chief Counsel to help formulate a response. Good Dep. 86-87. The DEA's copy of the letter includes the initials of DEA employees who reviewed the letter. Scott Collier identified these individuals as Cathy Brooks, Betsy Willis from the Domestic Drug unit, Andy McFaul, Scott Collier, Brian Bayly, and Bill Williamson, the deputy chief of Liaison and Policy Section. Collier Dep. 45-47.

On April 12, 2004, Good signed and mailed the letter responding to Mudri's letter. Pl. Ex. F. Good's letter began by quoting the statement from the Jones letter that storage of List I chemicals at or distribution from any unregistered location violates federal law. Good provided three scenarios to clarify the DEA's policy on overnight storage of List I chemical

products in delivery vehicles when a sales representative is unable to return to a registered location at the end of the day.

Scenario One stated that a sales representative who cannot complete his deliveries and return to a registered location at the end of a day because of a long delivery route is permitted to keep List I chemicals overnight in a locked, secure vehicle if: the List I chemicals are not visible, the sales representative is filling a pre-placed customer order, the sales representative is an employee of the company, the vehicle is company owned or leased or is a dedicated vehicle used only for the company's products, and the sales representative is required to stay overnight at a motel because of the length of his route. Pl. Ex. F at 1. The letter stated that the DEA considers List I chemical products to be "in transit" if all of these conditions are met. The DEA does not consider the products to be "in transit" if they are stored in a locked room or vehicle at a sales representative's home.

Scenario Two stated that sales representatives who pick up "general orders" of List I chemical products, as opposed to pre-placed customer orders, must return the products to a registered location at the end of the day. The DEA did not consider the List I chemicals to be "in transit" in this situation because there is no order for a specific customer. Pl. Ex. F at 2. Storage in a delivery vehicle overnight and subsequent distribution to customers would violate

federal law because the sales representative would be distributing from an unregistered location.[2]

Good distributed her letter to several other individuals. She blind carbon-copied employees in the St. Louis field division and the Kansas City district office. Dan Raber, Diversion Group Supervisor at the Indianapolis field office, obtained a copy of the letter, though it is not clear exactly how. Good testified that her office often sends copies of correspondence to program managers in each district office when the subject matter might affect an industry that has multiple locations throughout the country. Good Dep. 53. Good's office maintains a repository of letters that program managers across the country can access. *Id.* Good placed her April 12, 2004 letter in this repository. It is also possible that the DEA distributed the letter to all program managers by mail or at a conference.

After Raber read the Good letter, he felt the need to inform registrants in Indiana of the interpretation of the regulations by the central office of the DEA. Raber Dep. 68. He wanted registrants to be aware of the interpretation so that they could comply with federal law. Raber conferred with Thomas Crow, the diversion program manager in Chicago, to make sure he was aware of the Good letter and to obtain

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[2] Scenario Three dealt with freight-forwarding of List I chemical products. Novelty does not contest the validity of the DEA's policy stated in Scenario Three.

permission to send a letter to all Indiana registrants that included the information from the Good letter.

Madeline Kuzma, a diversion investigator in the Indianapolis office, testified that when she first read the Good letter, she thought it announced a new DEA policy. She believed it was necessary to distribute the information to the regulated businesses. Kuzma Dep. 30-31. Kuzma wrote an email on April 18, 2004 that stated that she was aware that Novelty and one other distributor of List I chemicals in Indiana were using unregistered storage sheds and vehicles for overnight storage. She wrote that she believed this was an issue that would "need addressing on a divisional, if not national level, to assure consistency and fairness. . . ." Pl. Ex. K at 1. She also wrote in the same email:

> If a strict interpretation of 1309.23(a) is to be applied, notification of the registration requirement for off-site storage/distribution needs to be made clearly to the registrant community, through federal register or field office letters to List 1 distributors in their jurisdiction – so companies can decide to seek registrations or change distribution procedures.

Id. at 2.[3] Kuzma testified that she and her colleagues in the Indianapolis office had not advised registrants

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[3] The cited regulation, 21 C.F.R. § 1309.23, provided:

(a) A separate registration is required for each principal place of business at one general physical

(Continued on following page)

that they were not permitted to use remote storage locations. When she became aware that the DEA interpreted the regulations to make it unlawful to distribute List I chemicals from remote storage locations and vehicles, she believed that the Indianapolis office was obligated to communicate this interpretation to registrants. Kuzma Dep. 38-39.

Dan Raber sent a letter to all registrants in Indiana on May 5, 2004. Pl. Ex. D. The letter began by "reminding" the registrants that "any storage at, and distribution from, a location other than the registered location (including the use of delivery vehicles for overnight storage) is a violation of federal law." *Id.* This statement, which is a direct quotation from the Jones letter, appeared in quotation marks but without attribution to any source. The letter next

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location where List I chemicals are distributed, imported, or exported by a person.

(b) The following locations shall be deemed to be places not subject to the registration requirement:

(1) A warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered; and

(2) An office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals (other than chemicals for display purposes) nor serves as a distribution point for filling sales orders.

stated: "Hopefully the three scenarios presented below will help clarify overnight storage of List I chemical products in delivery vehicles when the length of a sales representative's delivery route requires the person to stay overnight at motels and precludes him or her from returning to the registered location at the end of the day." *Id.* The letter then set forth the three scenarios from the Good letter, using language that was almost identical to the language in the Good letter.

Discussion

I. *Jurisdiction*

A. *Section 877*

Section 877 of the CSA provides that the United States Court of Appeals for the District of Columbia Circuit and the Court of Appeals for the circuit in which the principal place of business of the party seeking review is located have exclusive jurisdiction to review "final determinations, findings, and conclusions" of the Attorney General with respect to the CSA. 21 U.S.C. § 877. On August 15, 2006, the court issued an entry on the defendants' motion to dismiss that discussed at length the issue of this court's jurisdiction. *Novelty, Inc. v. Tandy,* 2006 WL 2375485 (S.D. Ind. Aug. 15, 2006). In brief summary, the court held that § 877 does not apply because Novelty is not challenging a "final determination, finding, or conclusion" by the DEA that was developed through formal procedures and that had

created a record suitable for judicial review. The CSA uses the terms determinations, findings, and conclusions only in the context of the Attorney General using procedures that give affected persons some sort of notice, an opportunity to be heard, an opportunity to develop a formal record of the agency action, and an opportunity for judicial review of the agency decision. *Id.* at *2-3, citing 21 U.S.C. §§ 811(a), 812(b), 823, and 824. Raber's letter to Novelty was not preceded by notice to the registrants, an opportunity to be heard, or an opportunity to develop a formal record.

The court relied on the Supreme Court's reasoning in *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 497 (1991), which emphasized the importance of providing a meaningful opportunity for review based on an adequate record. The court recognized that other courts had found that § 877 deprived district courts of jurisdiction to review some arguably similar claims under the CSA. See *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004), *aff'd, Gonzales v. Oregon*, 546 U.S. 243 (2006); *John Doe, Inc. v. Gonzalez*, 2006 WL 1805685 (D.D.C. June 29, 2006). In *John Doe, Inc. v. Gonzalez*, the court considered whether § 877 applied to a challenge to a DEA decision to revoke the plaintiff's permit to import a substance. The plaintiff could have requested a hearing to contest the revocation of the permit or submitted materials stating its position to the agency, but chose to file suit in federal court instead. In contrast, Novelty had no alternative mechanism for developing

a record or obtaining judicial review, other than deliberately violating the requirements as set out in the Raber letter and defending itself in an enforcement action. The court concluded that § 877 did not bar the court's jurisdiction because, without jurisdiction in a district court, Novelty would be left without a forum for meaningful review of its claim. *Novelty,* 2006 WL 2375485, at *9.

The defendants argue that the court should reconsider its view of § 877 based on the affirmance of the *John Doe, Inc.* decision by the District of Columbia Circuit. See 484 F.3d 561 (D.C. Cir. 2007). The court has reviewed the District of Columbia Circuit's opinion, including that court's discussion of this court's entry on the motion to dismiss. Respectfully, and in light of *McNary,* the court finds no reason to change its position on the applicability of § 877. This court made it clear in its entry on the motion to dismiss that it agreed with the result in *John Doe, Inc.* because of the availability of alternative mechanisms for judicial review, but disagreed only with the broad conclusions of the district court that § 877 encompasses all CSA-related final agency actions. *Novelty,* 2006 WL 2375485, at *5-6. Here, the court continues to find that the DEA's actions would not be subject to meaningful judicial review absent district court jurisdiction, at least without requiring Novelty or similarly situated businesses to risk enforcement action against them by the DEA.

B. *Finality*

The Administrative Procedure Act ("APA") provides that only agency actions made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. 5 U.S.C. § 704. To be "final," an agency action must satisfy two conditions: (1) it must mark the completion of the agency's decision-making process, as opposed to being a tentative action; and (2) the action must be "one by which rights or obligations have been determined, or from which legal consequences flow." *Home Builders Association of Greater Chicago v. U.S. Army Corps of Engineers,* 335 F.3d 607, 614 (7th Cir. 2003), quoting *Bennett v. Spear,* 520 U.S. 154, 178 (1997).

In its entry on defendants' motion to dismiss, the court held that the Raber letter's use of scenarios did not preclude the court from finding that it amounted to a final agency action because the letter announced an unequivocal position. *Novelty,* 2006 WL 2375485, at *11. The court permitted Novelty to pursue discovery so that it could present evidence to support its contention that the Raber letter was part of a nationwide effort on the part of the DEA to alter List I chemical storage requirements. *Id.* at *12.

Novelty has presented evidence that Raber's letter was in fact part of such an effort. Raber's letter was based on Good's letter, which was written, reviewed, and approved by a number of DEA employees. Good was the chief of the Liaison and Policy

section of the DEA's Diversion Control Office. The defendants argue that Good was not authorized to make final rules or take final agency action on behalf of the DEA. However, there is no dispute that Good was authorized to send the letter to John Mudri. Collier Dep. 35. The plaintiff reported that Good stated in her deposition that one of her section's responsibilities was to communicate DEA policy to the public. "The policy would be developed at a higher level, but communicated, interpreted and more or less put in writing by my section." Pl. Br. 11 (citing, but not including, page 14 of Good Dep.). The letter was reviewed and approved by other members of the Liaison and Policy Section, two members of the Chemical Investigation section, an employee from the Domestic Drug Unit, and an employee from the Office of the Chief Counsel. Collier Dep. 42-51, Good Dep. 85-90. The DEA has not argued that the Good and Raber letters do not reflect accurately the agency's position on the storage requirements for List I chemicals.

Good's letter was made available to all diversion investigators and field offices through the DEA's letter repository and was possibly also sent to all district program managers and/or distributed at a national conference. Dan Raber received Good's letter and sent his own version of the letter to all Indiana registrants. Prior to sending his letter, Raber got approval from Thomas Crow, the district program manager from Chicago, who supervised the Indianapolis office. The court is satisfied that the Raber letter reflects the completion of the DEA's decision-making process

on this issue and that the DEA intended for all district offices to follow the rules announced in the letter.

The Raber letter was an action that determined rights or obligations or from which legal consequences flow. Approximately fifty registrants received the letter from Raber. The letter notified at least some of these registrants that their distribution practices violated federal law, which put them at risk of having their registrations revoked and being subjected to criminal prosecution. The DEA included the exact language of a large portion of Scenario One from the Good letter in a letter of admonition to a registrant in Missouri. Pl. Ex. N. Mark Caverly testified for the DEA that a letter of admonition is a "formal written vehicle that a local office will use, at the conclusion of an on-site regulatory investigation, to note violations and request a written response from the company, as to what action has been taken." Caverly Dep. 63. He described a letter of admonition as an enforcement tool for the DEA. *Id.*

That specific letter of admonition informed the registrant that a recent inspection showed several deficiencies, including failure to adhere to DEA policy regarding the unauthorized practice of storing List I chemicals in places other than registered locations. Pl. Ex. N. The letter stated that List I chemicals could be kept overnight in a locked, secure vehicle only if they were not visible and listed the additional conditions from the Good letter using the precise

language of the Good letter. *Id.* The letter went on to state:

> List I chemical products may NOT be stored at a sales representative's home or at a remote location (such as a storage locker, etc.) either in a locked and secured vehicle or otherwise. This applies to customer specific and non-customer specific orders containing List I chemical products. List I chemicals may only be distributed from a registered location.

Id.

This letter summarizes the contents of both the Good and Raber letters. Thus, the court finds that the Good letter, which is identical in substance to the Raber letter, has been enforced by the DEA. The Raber letter thus created new obligations for registrants, and legal consequences have flowed from it. The letter is therefore a final agency action that is subject to judicial review.

II. *Interpretive Rules and Legislative Rules*

The APA defines a rule as the "whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency . . . " 5 U.S.C. § 551(4). This definition includes agency statements that legislate as well as those that interpret existing law and regulations. In

general, when an executive agency wants to promulgate a rule, it must provide notice and an opportunity for comment, and it must issue a concise general statement of the rule's basis and purpose. 5 U.S.C. § 553. The APA exempts from these requirements "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(3)(A); *Lincoln v. Vigil,* 508 U.S. 182, 196 (1993). The APA does not define the term "interpretive rules."

The distinction between a legislative rule, which requires an agency to follow notice-and-comment procedures, and an interpretive rule, which does not require those procedures, is both elusive and critical in administrative law. As the Seventh Circuit explained in *Hoctor v. United States Department of Agriculture,* 82 F.3d 165, 167 (7th Cir. 1996):

> Notice and comment rulemaking is time-consuming, facilitates the marshaling of opposition to a proposed rule, and may result in the creation of a very long record that may in turn provide a basis for a judicial challenge to the rule if the agency decides to promulgate it. There are no formalities attendant upon the promulgation of an interpretive rule, but this is tolerable because such a rule is "only" an interpretation.

The distinction has important consequences for the agency, the regulated community, and the public in general. On one hand, agencies must have some flexibility and must be able to explain ambiguous terms in

the statutes and regulations they are charged with enforcing. See *Metropolitan School District of Wayne Township v. Davila,* 969 F.2d 485, 492 (7th Cir. 1992), citing *American Hospital Ass'n v. Bowen,* 834 F.2d 1037, 1045 (D.C. Cir. 1987). On the other hand, the APA's notice-and-comment provisions reflect Congress' desire to provide some checks on agency authority. Notice-and-comment procedures give members of the public an opportunity to communicate their concerns and suggestions to agencies that have been delegated legislative authority but are not elected by the public. See *Hoctor,* 82 F.3d at 171; *American Hospital Ass'n,* 834 F.2d at 1044.

This critical distinction is also elusive, as shown by the case law discussed below. Deciding whether a rule or agency policy statement is interpretive or legislative can be akin to deciding whether a particular spot is in the foothills or in the mountains, or deciding whether to describe the weather as "partly cloudy" or "partly sunny." This case lies somewhere in the higher foothills or lower mountain slopes.

A. *Seventh Circuit Precedent*

The defendants argue that the court should decide the legislative v. interpretive rule issue by considering the factors that the District of Columbia Circuit set out in *General Motors Corp. v. Ruckelshaus,* 742 F.2d 1561 (D.C. Cir. 1984) (en banc), as discussed in *Metropolitan School District of Wayne Township v. Davila,* 969 F.2d at 489-90. Davila was

the Assistant Secretary for Special Education and Rehabilitative Services within the United States Department of Education. He received an inquiry about whether the Individuals with Disabilities Education Act ("IDEA") required states to provide educational services to disabled children who were expelled or suspended for extended periods of time for reasons unrelated to their disabilities. Davila responded to the inquiry in a letter stating that the Department of Education interpreted the IDEA to require states to provide educational services in these circumstances. The school district challenged the rule as invalid, arguing that it had been promulgated without notice and comment. *Davila,* 969 F.2d at 487. The district court granted summary judgment in favor of the school district. The Seventh Circuit reversed, holding that the rule was only interpretive.

The Seventh Circuit noted that the District of Columbia Circuit had set out general principles by which to determine whether a rule is interpretive or legislative in *General Motors Corp. v. Ruckelshaus,* 742 F.2d at 1565. The first principle is how the agency itself characterized the rule, which is a relevant but not decisive factor. *Davila,* 969 F.2d at 489. Next, an interpretive rule states what the agency thinks the statute means and reminds parties of their existing duties, while a legislative rule creates new laws, rights, or duties. *Id.* at 489-90. The Seventh Circuit also noted that it had previously cited with approval Professor Kenneth Davis' test for distinguishing between interpretive and legislative

rules, which focuses on whether the agency exercised delegated power to make law. For example, if an agency has not been given the authority to make law, its rule must be interpretive. However, the court stated that Professor Davis' test has limited value when the agency has been delegated both rulemaking authority and the authority to issue interpretive rules. *Id.*

The *Davila* court went on to apply the *General Motors* principles. First, the agency's letter stated that it was an interpretation of the IDEA based on a recent Supreme Court decision, other cases interpreting the IDEA, the language of the IDEA and an implementing regulation, and the legislative history of the IDEA. *Id.* Next, the court discussed whether the letter created new law, rights, or duties. The court concluded that while the position announced in the letter was new, it was not necessarily legislative. *Id.* at 492, citing *Michigan v. Thomas,* 805 F.2d 176, 183 (6th Cir. 1986) (holding that the EPA's new definition of the term "reasonably available control technology" was interpretive even though it required more of the states than the previous definition); *Alcaraz v. Block,* 746 F.2d 593, 613-14 (9th Cir. 1984) (holding that rule that required families to provide Social Security numbers of all adults in the household before students could receive free or reduced price meals at school was interpretive even though it altered administrative duties); *American Postal Workers Union v. United States Postal Service,* 707 F.2d 548, 558-60 (D.C. Cir. 1983) (holding that the Postal

Service's rule changing the computation formula for retirement benefits was interpretive). "These cases show that an agency's change in its reading of a statute does not necessarily make the rule announcing the change legislative. That rules 'may have altered administrative duties or other hardships does not make them substantive [legislative].'" *Davila,* 969 F.2d at 492, quoting *Alcaraz,* 746 F.2d at 613. The court also stated that a rule that affects rights and obligations is not necessarily legislative. *Id.* at 493, citing *Production Tool Corp. v. Employment and Training Admin.,* 688 F.2d 1161, 1166 (7th Cir. 1982).

The Seventh Circuit introduced an additional principle while summarizing its reasons for concluding that the rule at issue was interpretive:

> It relies upon the language of the statute and its legislative history. . . . This represents the paradigmatic case of an interpretive rule. . . . The rule is based on specific statutory provisions . . . and its validity stands or falls on the correctness of the agency's interpretation of the statute. In these circumstances, it is clear that the rule is an interpretive one.

Davila, 969 F.2d at 492. The rule in *Davila* imposed a new duty on school districts to provide educational services for disabled students who had been expelled or suspended. However, the court was persuaded that the agency's reliance on the language and legislative history of the statute in creating the rule made the rule interpretive.

In *Hoctor v. United States Department of Agriculture,* the Seventh Circuit also decided whether an agency rule was legislative or interpretive. 82 F.3d at 167. The Department of Agriculture had promulgated a regulation under the Animal Welfare Act stating that facilities housing animals must be constructed "of such material and of such strength as appropriate for the animals involved." 9 C.F.R. § 3.125(a). The Department of Agriculture then issued an internal memorandum to its inspectors stating that all "dangerous animals" must be inside a perimeter fence at least eight feet high. Hoctor, the plaintiff, was an exotic animal dealer who raised a variety of "dangerous animals" that he enclosed in a six foot high fence. *Hoctor,* 82 F.3d at 168. The Department of Agriculture cited Hoctor on several occasions for not having an eight foot fence and ultimately imposed sanctions on him. Hoctor challenged the sanctions on the basis that the eight foot rule was invalid because the Department of Agriculture had not followed the notice and comment procedures the APA requires. The Department of Agriculture argued that the rule was an interpretation of the regulation.

The court explained that a rule is interpretive only "if it can be derived from the regulation by a process reasonably described as interpretation," *Id.* at 170, citing *Davila,* 969 F.2d at 490. The court found that the eight foot fence rule was not interpretive because "[t]here is no process of cloistered, appellate-court type reasoning by which the Department of

Agriculture could have excogitated the eight-foot rule from the structural-strength regulation." *Id.* at 171. Rather than interpreting the regulation, the court found that the agency had made an arbitrary choice that the containing fences must be eight feet high. Legislators are elected by the public to make choices that involve arbitrary choices or value judgments. Agencies do not have this "democractic [sic] legitimacy," and must follow the notice-and-comment procedures when proposing to make rules based on arbitrary choices. *Id.* at 170-71.

Finally, the *Hoctor* court did not place any weight on the agency's own characterization of the rule: "we think the agency's 'intent,' though a frequently cited factor, is rather a make-weight. What the agency intends is to promulgate a rule. It is for the courts to say whether it is the kind of rule that is valid only if promulgated after notice and comment." *Id.* at 172.

In *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers,* 191 F.3d 845, 852 (7th Cir. 1999), *reversed on other grounds,* 531 U.S. 159 (2001) (holding rule invalid because Corps exceeded its authority under Clean Water Act), the Seventh Circuit held that a rule that defined "waters of the United States" to include any water that was the habitat of migratory birds that cross state lines was interpretive. The Army Corps of Engineers had written a letter to SWANCC stating that the Corps intended, based on the Migratory Bird Rule, to exercise jurisdiction over the site SWANCC had selected for waste storage. *Id.* at 848-49. The Seventh

Circuit distinguished the case from *Hoctor*. The statute in *Hoctor* did not impose a duty to build a fence of any particular height. The statute authorized the agency to impose a specific obligation to implement the general statutory goals. Instead of stating a specific obligation in regulations issued through notice-and-comment procedures, the agency in *Hoctor* provided a vague standard in the regulations and made its specific value judgment in the eight foot fence rule. In contrast, the Clean Water Act defined the waters over which the Corps had jurisdiction by using the term "navigable waters." The agency had elaborated further on that definition in its regulations by using the term "waters of the United States." These vague definitions provided the agency with at least "something to interpret" through interpretive rules, not just a vague standard. *Id.* at 852.

The defendants have argued that the court should also consider whether the statutory scheme would have been operative even without the rule. The District of Columbia Circuit discussed that factor in *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993). The court stated that if, in the absence of the rule, there would be no legislative basis for an enforcement action or other agency action to confer benefits or to ensure the performance of duties, the rule must be legislative. *Id.* The court did not state that the inverse would also be true; the court did not state that if in the absence of the rule there was a basis for

enforcement actions, the rule must be interpretive. Here, there is no dispute that the DEA may bring an enforcement action against a registrant even in the absence of the Raber and Good letters. This factor tends to weigh somewhat in favor of finding the letters were interpretive.

The critical distinction between interpretive and legislative rules remains "far from crystal-clear," *Chemical Waste Management, Inc. v. United States Environmental Protection Agency,* 869 F.2d 1526, 1534 (D.C. Cir. 1989), and "enshrouded in considerable smog." *General Motors,* 742 F.2d at 1565; accord, *American Mining Congress,* 995 F.2d at 1112 ("insofar as our cases can be reconciled at all. . . ."). Nevertheless, the Seventh Circuit has identified several factors for a court to consider to determine whether a rule is legislative or interpretive. The court should consider the agency's characterization of the rule; the type of reasoning the agency used to formulate the rule from the regulations; and whether the rule creates new duties, rights, or obligations. The rule is interpretive if the agency used appellate-court type reasoning, including reference to sources such as the text of the statute and regulations, the statute's legislative history, and case law. *Davila,* 969 F.2d at 492; see also *SWANCC,* 191 F.3d at 852. Even if a rule creates new duties, rights, or obligations, the rule is interpretive if it simply clarifies an existing statute or regulation. *Davila,* 969 F.2d at 489. If the agency created a specific rule from a vague standard that did not provide the agency with "something to

interpret," the rule is legislative. *Hoctor,* 82 F.3d at 170.

B. *The Raber Letter*

1. *The DEA's Characterization of the Letter*

The defendants argue that the texts of the letters demonstrate that the DEA characterized the letters as interpretive when they were written. The Jones letter began with a statement that its purpose was to "remind" all List I chemical distributors of federal requirements regarding registration. The Jones letter cited 21 U.S.C. § 822(e), which requires registrants to obtain a separate registration for each principal place of business where it manufactures, distributes, or dispenses List I chemicals. The letter also cited 21 C.F.R. § 1309.23, which requires registrants to obtain a separate registration for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported. Pl. Ex. H. The Good letter did not include citations to federal law, but stated that Mr. Mudri had requested clarification on overnight storage of List I chemicals in delivery vehicles and that Good was providing clarification. Pl. Ex. F at 1. Similarly, the Raber letter did not cite to federal law, but stated that its goal was to "help clarify overnight storage of List I chemical products in delivery vehicles. . . ." Pl. Ex. D at 1.

Though this factor weighs in favor of the Raber letter being interpretive, the court agrees with Judge Posner's assessment in *Hoctor* that this factor is

"rather a make-weight." When an agency has not gone through notice-and-comment procedures to develop a policy, it is hard to imagine that it would characterize its policy or rule as anything other than interpretive. The court has not assigned this factor significant weight.

2. *The DEA's Method of Reasoning*

The CSA requires manufacturers and distributors of List I chemicals to be registered with the DEA. 21 U.S.C. § 822(e) states: "A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals." Several regulations provide additional guidance as to the registration requirements. 21 C.F.R. § 1309.23(a) states: "A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported by a person." The regulation provides an exception to the registration requirement for a warehouse where List I chemicals are stored by a registered person if the chemicals are distributed directly from the warehouse to the location from which the chemicals were originally delivered. § 1309.23(b)(1). There is also an exception to the registration requirement for offices used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which contain no chemicals and do not serve as a distribution points [sic] for filling sales orders. § 1309.23(b)(2).

On its face, this regulation requires the registrant to obtain a separate registration for each general physical location from which the registrant plans to distribute List I chemicals. However, the regulation does not define the terms "principal place of business" or "one general physical location." It also does not specify whether a separate registration is required for storage of List I chemicals.

A second relevant regulation, 21 C.F.R. §1309.24(a), states: "The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his or her business or employment." On its face, the regulation provides that an agent or employee of a registered person is not required to be registered to be able to perform his or her usual course of business or employment for the registered person. This regulation eliminates the need for an employer to obtain registrations for each individual employee or agent. However, the regulation does not define the term "usual course of business."

Finally, 21 C.F.R. § 1309.71(a) provides: "All applicants and registrants must provide effective controls and procedures to guard against theft and diversion of List I chemicals." The regulation goes on to list a number of factors the DEA should consider when determining whether an applicant for registration's security procedures are effective, including factors related to the applicant's facilities, the level of supervision over employees who have access to the

chemicals, and the adequacy of the applicant's systems for monitoring the receipt, distribution, and disposition of the chemicals in its operations. 21 C.F.R. § 1309.71(b).

The Good and Raber letters began by stating a general rule that storage in and distribution from any place that is not registered violate federal law.[4] The ambiguous terms "principal place of business" and "one general physical location" in § 1309.23 are examples of language that is ripe for agency interpretation. See *SWANCC*, 191 F.3d at 852; *Hoctor*, 82 F.3d at 170. It is possible to interpret the regulation to require registrants to obtain separate registrations for each separate physical location from which they distribute, import, or export List I chemicals. It is also possible to interpret the requirement to obtain a separate registration for each place from which List I chemicals are "distributed" to include places in which List I chemicals are stored overnight en route to being distributed. By this interpretation, for example, if a sales representative wanted to store List I chemicals in a delivery vehicle overnight while on her way to distribute them, she would be required to obtain a registration for the delivery vehicle. The language of the regulation thus provides some basis

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[4] In its Complaint, Novelty challenged this general rule as inconsistent with the CSA and its implementing regulations. Cmplt. ¶ 30, quoting 21 U.S.C. § 822(e) and 21 C.F.R. § 1309.23. Novelty has not discussed or developed this argument in its briefs in support of its motion for summary judgment.

from which the DEA could have interpreted the general rule it announced in the Good and Raber letters that sales representatives may not store or distribute products containing List I chemicals in unregistered locations.

The first scenario outlined in the Raber letter provides an exception to the general rule that sales representatives may not store products containing List I chemicals in unregistered locations. If a sales representative cannot return to a registered location at the end of the day because he has a long delivery route, he may keep List I chemicals overnight in a locked secure vehicle while he stays overnight at a motel, so long as a number of conditions are met. The Raber letter specifies that this exception does not apply to sales representatives who stop overnight at their homes. Pl. Ex. D at 1.

21 C.F.R. §§ 1309.24(a) and 1309.71 provide a basis for the rule announced in this scenario. The DEA has interpreted the term "usual course of business" from § 1309.24(a) to include sales representatives who are en route to their final destinations, but not to sales representatives who return to their homes. Collier Dep. 63. The DEA has also determined that a sales representative who stays at her home overnight with List I chemicals stored in her delivery truck does not provide "effective controls and procedures to guard against theft and diversion" as required by § 1309.71.

Based on its interpretation of § 1309.23, it would have been permissible for the DEA to conclude that List I chemicals could never be stored overnight in delivery vehicles under any circumstances, whether at motels, homes, or restaurants. In enforcing the regulation, however, the DEA has decided to introduce some degree of practical flexibility to accommodate the regulated industry. Nothing in the regulation itself requires that flexibility. In the Good and Raber letters, the DEA announced, in effect, that it would tighten up its enforcement in some respects (*e.g.*, home stays) but not others (motel stays). Preserving the exception for motel stays makes it possible for companies like Novelty to continue to utilize long delivery routes while also keeping the List I chemicals relatively more secure.

In the second scenario, the DEA set an additional limit on the types of orders that may be stored overnight in delivery trucks. A load that includes preplaced customer specific orders may be stored overnight in a delivery vehicle provided it meets the requirements discussed in the first scenario. However, the DEA has determined that the exception to the registration requirement does not apply to sales representatives who have "general orders" in their vehicles. If the load includes a general order, the Raber letter states: "the DEA does not consider the List I chemical products to be in transit (no customer specific order). . . ." Pl. Ex. D at 2. This is a permissible interpretation of ambiguous language in § 1309.24(a). Again, based on its interpretation of

§ 1309.23, it would have been permissible for the DEA to conclude that List I chemicals could never be stored overnight in delivery vehicles. Thus, it was permissible to limit the ability to store List I chemicals in storage vehicles overnight to loads containing only pre-placed customer specific orders.

Novelty argues that the DEA's distinctions between motels and homes and between specific orders and general orders do not make sense as a matter of sound policy. Whether those distinctions are sound policy is not the issue before the court. In deciding whether the Good and Raber letters are interpretive or legislative agency actions, the relevant point is that the text of the applicable regulations does not require the DEA to allow any of the exceptions. In deciding to tighten its enforcement policy to some extent, the DEA was trying to act as executive agencies often act: adjusting the formal law to accommodate some practical realities in a way that remains faithful to the language and purpose of the duly promulgated statutes and regulations. Not every detail of such accommodation is a further legislative act.

3. *New Duties, Rights, or Obligations*

The general rule regarding registration requirements and the two scenarios discussed in the Raber letter were changes in policy for the Indianapolis field office. Prior to this letter, the Indianapolis office was aware that Novelty and other registrants permitted

their sales representatives to store products containing List I chemicals (for both pre-placed and general orders) in their vehicles overnight while they stayed at their homes or at motels. Kuzma Dep. 51-52. The DEA had not expressed disapproval of this practice during the pre-registration investigation of Novelty in 1998 or in any of the subsequent periodic inspections of Novelty. Kuzma Dep. 51-54. Prior to the Raber letter, the Indianapolis field office had interpreted 21 C.F.R. § 1309.24(a) in a manner that permitted sales representatives to store List I chemical products in their vehicles as long as they were secure. Kuzma wrote in an April 18, 2004 email:

> Previously, the practical interpretation in the field has included that the route personnel were acting as an agent of the registrant and the product just had to be secured in some manner – locked truck, residence, etc., but a separate registration was not required as the product that originated at the registered location was distributed to the customer via route employees. In years past, I did not instruct registrants to cease such dist. procedures and the Chemical Section, which was on distribution for the 6s (investigative reports), never raised an issue.

Pl. Ex. K.

As discussed above, one factor the court must consider is whether the rules created new law, rights or duties. The rules announced in the Raber letter require Novelty to change its distribution practices

significantly. Sales representatives will be obligated to store all List I chemical products at a registered location before being able to stay overnight at their homes. They will also be obligated to return all List I chemical products from general orders to a registered location at the end of each day. However, as discussed above, the fact that an agency has announced a new enforcement policy based on a new, stricter interpretation of a regulation does not necessarily make the rule legislative. *Davila,* 969 F.2d at 490.

One key to distinguishing between a legislative and an interpretive rule is whether the rule relies upon the language of the statute or the implementing regulations. Here, the DEA relied upon 21 C.F.R. §§ 1309.23, 1309.24(a), and 1309.71 in formulating the general rule and scenarios announced in the Raber letter. The stricter interpretation of the regulations was undoubtedly related to the discovery of many incidents of theft of List I chemicals from delivery vehicles. The tighter enforcement policy set forth in the Raber and Good letters reflects, in the court's judgment, simply a tighter interpretation of broad existing regulations. DEA was not required to allow any exceptions to those regulations. Its decision to allow some exceptions and to explain them to the regulated industry was not a legislative action subject to the notice-and-comment procedures of the APA.

Conclusion

For the reasons discussed above, the court grants the defendants' motion for summary judgment and denies plaintiff's motion. The court will enter final judgment for the defendants.

So ordered.

Date: August 7, 2008

/s/ David F. Hamilton
DAVID F. HAMILTON,
CHIEF JUDGE
United States District Court
Southern District of Indiana

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REGULATIONS CITED

21 C.F.R. § 1309.54(b)

(b) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) are satisfied.

STATUTES CITED

5 U.S.C. § 706

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall –

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be –

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

---

21 U.S.C. § 822(a)(1)

(a) Period of registration

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

---

21 U.S.C. § 822(c)(1)

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

---

21 U.S.C. § 822(e)

(e) Separate registration

A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

---

21 U.S.C. § 823(b)(1)

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the

public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

---

21 U.S.C. § 823(h)

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 802(39)(A) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider –

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

> (4) any past experience of the applicant in the manufacture and distribution of chemicals; and
>
> (5) such other factors as are relevant to and consistent with the public health and safety.

---

28 U.S.C. § 1254(1)

Cases in the courts of appeals may be reviewed by the Supreme Court by the following methods:

> (1) By writ of certiorari granted upon the petition of any party to any civil or criminal case, before or after rendition of judgment or decree[.]

[LOGO] **U. S. Department of Justice**
Drug Enforcement Administration
Indianapolis District Office
575 North Pennsylvania St., Room 408
Indianapolis, Inndiana [sic] 46204

---

www.dea.gov May 5, 2004

Novelty Distributors ***CONFIDENTIAL***
dba Greenfield Labs
351 West Muskegon Drive
Greenfield, Indiana 46140

Dear Registrant:

This correspondence pertains to the transportation and delivery of List I chemicals by sales representatives for List I chemical registrant's to retail customers. The below scenarios are provided in case you are storing List I chemical products (including over-the-counter ephedrine and pseudoephedrine items) and distributing them from satellite locations, such as commercial storage units, personal residences and or delivery vehicles. The Indianapolis District Office reminds all registrants that "any storage at, and distribution from, a location other than the registered location (including the use of delivery vehicles for overnight storage) is a violation of federal law".

Hopefully the three scenarios presented below will help clarify overnight storage of List I chemical products in delivery vehicles when the length of a sales representative's delivery route requires the person to stay overnight at motels and precludes him

or her from returning to the registered location at the end of the day.

Scenario One

If company sales representatives of List I chemical products pick up the List I chemical products including ephedrine and pseudoephedrine drug products at a registered location and cannot return to the registered location at the end of the day because they have a long delivery route, they may keep the List I chemical products overnight in a locked secure vehicle provided the List I chemicals are not visible and the following conditions are met:

- The sales representatives are filling *pre-placed customer specific orders for the List I chemical products* (that is, they are not deciding at the customer locations how much List I chemical products to leave and are not seeking new orders);
- The sales representative's are employees of the company;
- The delivery vehicles are either company owed [sic] or leased, or are dedicated vehicles used only for the company's products; and
- The sales representatives are required to stay overnight at a motel because of the length of their routes.

DEA considers the List I chemical products to be intransit if all of the above conditions are met. However, List I chemical products may NOT be

stored in a locked and secure vehicle at a sales representative's home. DEA does not consider the List I chemical products to be in transit in this case.

Scenario Two

If company sales representatives of List I chemical products pick up a "*general order*" of List I chemical products including ephedrine and pseudo-ephedrine drug products as opposed to pre-placed customer specific orders for these products, and cannot return to the registered location at the end of the day because they have a long route, they may **NOT** keep the List I chemical products overnight in a locked secure vehicle. In this case DEA does not consider the List I chemical products to be in transit (no customer specific order) and if the List I chemical products are kept in the delivery vehicle overnight and then sold, DEA considers the sales representative to be distributing from an unregistered location (the delivery vehicle). This is a violation of federal law.

Scenario Three

DEA is aware that sometimes a company ships orders containing List I chemicals to sales representatives at remote locations. DEA considers this to be freight forwarding and at this time DEA has no provisions that would permit freight forwarding for List I chemical products.

If you have any questions about this clarification, you may contact the Indianapolis Diversion Group at (317) 226-7977.

Sincerely,

Dan E. Raber
Diversion Group Supervisor

[LOGO] **U.S. Department of Justice**
Drug Enforcement Administration

[Illegible] [Illegible]

IN THE MATTER OF

Novelty Distributors
d/b/a Greenfield Labs
351 West Muskegon Drive
Greenfield, Indiana 46140

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act. Title 21, United States Code, Sections 823 and 824.

NOTICE is hereby given: (1) to inform Novelty Distributors, d/b/a Greenfield Labs ("Novelty"), of the immediate suspension of its Drug Enforcement Administration (DEA) Certificate of Registration, 003563NSY, as a distributor of list 1 chemicals, because such registration constitutes an imminent danger to the public health and safety, pursuant to 21 U.S.C. § 824(d); and (2) to afford Novelty an opportunity to Show Cause before DEA, at 600 Army Navy Drive, Arlington, Virginia, on March 24, 2008, at 9:00 a.m., as to why DEA should not revoke its registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. § 823(h),

because Novelty's continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. §§ 823(h) and 824(a)(4). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Novelty is registered with DEA as a distributor of the List 1 chemicals pseudoephedrine and ephedrine under DEA number 003563NSY, and its sole DEA registered location is 351 W. Muskegon Drive, Greenfield, Indiana 46140. Novelty's current DEA registration expires on October 31, 2008.

2. Novelty distributed, and continues to distribute, List 1 chemicals (specifically, scheduled listed chemical products) from over 100 unregistered locations in violation of 21 U.S.C. § 822(c) and 21 C.F.R. §§ 1309.21 and 1309.23(a). Novelty stores scheduled listed chemical products at unregistered storage facilities and other locations throughout the United States. Novelty's employees or agents then distribute scheduled listed chemical products directly from these unregistered locations to regulated sellers. Violating Federal laws relating to the handling of List 1 chemicals is conduct that is inconsistent with the public interest. *See* 21 U.S.C. §§ 823(h)(2) and 824(a)(4).

3. Novelty has distributed, and continues to distribute, large quantities of scheduled listed chemical products to small retail outlets such as convenience stores. The quantity of scheduled listed

chemical products that Novelty sells to some convenience stores far exceeds what those retail outlets could be expected to sell for legitimate, therapeutic purposes. The scheduled listed chemical products distributed by Novelty in large quantities have been, and are likely to continue being, diverted to the clandestine manufacture of methamphetamine as indicating by following non-exhaustive facts:

> a. In November 2002, 22 bottles of ephedrine products distributed by Novelty were found at an illicit methamphetamine laboratory in Connecticut.
>
> b. Small retail outlets that receive large quantities of scheduled listed chemical products from Novelty sell such products to individuals in amounts that cannot be attributed to legitimate individual needs. For example, some of the retail outlets allow customers to make multiple purchases of scheduled listed chemical products within a single week, and in some cases, within a single day. Some customers of these retail outlets purchased more than 9 grams of ephedrine or pseudoephedrine base within 30 days in violation of 21 U.S.C. § 844(a).

Excessive sales of scheduled listed chemical products that are or may be diverted to the clandestine manufacture of methamphetamine is conduct that is inconsistent with the public interest. See 21 U.S.C. §§ 823(h)(1), 823(h)(5) and 824(a)(4); *T. Young Associates, Inc., Revocation of Registration*, 71 Fed. Reg. 60,567 (2006); *Holloway Distributing: Revocation*

of Registration, 72 Fed. Reg. 42,118 (2007); *Planet Trading, Inc., d/b/a/ United Wholesale Distributors, Inc.: Denial of Application*, 72 Fed. Reg. 11,055 (2007).

4. In July 2007 DEA conducted an audit of Novelty's records and inventory for 20 scheduled listed chemical products distributed by Novelty. Novelty could not account for more than 60,000 dosage units of two ephedrine products. The audit also revealed overages for 16 different scheduled listed chemical products. Novelty failed to maintain accurate records of its distributions and receipts of scheduled listed chemical products in violation of 21 U.S.C. § 830(a) and 21 C.F.R. § 1310.04. Failure to comply with the record keeping requirements of Federal law is conduct that is inconsistent with the public interest. See 21 U.S.C. §§ 823(h)(2) and 824(a)(4).

5. From January 1, 2007, through July 9, 2007, Novelty distributed scheduled listed chemical products on at least 284 occasions to 35 retail outlets that were not self-certified under 21 U.S.C. § 830(e)(1)(A)(vii). Regulated sellers must be self-certified in order to sell any scheduled listed chemical product at retail. See 21 USC § 830(e)(1)(B)(i). Distributing scheduled listed chemical products to retail outlets that are not self-certified, and therefore cannot lawfully sell scheduled listed chemical products, is conduct that is inconsistent with the public interest. See 21 U.S.C. §§ 823(h)(2), 823(h)(5) and 824(a)(4).

6. Novelty distributed 24-count bottles of scheduled listed chemical products on three occasions to retail outlets after February 1, 2007. As of April 9, 2006, non-liquid schedule listed chemicals could not be lawfully sold at retail except when packaged in blister packs containing no more than two dosage units per blister. See 21 U.S.C. § 830(d)(2). Distributions of 24-count bottles of scheduled listed chemical products to retail outlets that cannot lawfully sell bottles of such products is conduct that is inconsistent with the public interest. See 21 U.S.C. §§ 823(h)(5) and 824(a)(4).

7. Novelty distributed tablet form scheduled listed chemical products to retail outlets located in two states, Kentucky and North Carolina, that prohibit the sale of non-liquid ephedrine and pseudoephedrine except in a gel-cap product. Distribution of scheduled listed chemical products in violation of state law is conduct that is inconsistent with the public interest. See 21 U.S.C. §§ 823(h)(2) and 824(a)(4).

IN view of the foregoing, and pursuant to 21 U.S.C. § 824(d). I find that the scheduled listed chemical products distributed by Novelty have been, and are likely to continue to be, diverted into the illicit manufacture of methamphetamine. Novelty has failed to maintain effective controls against such diversion as required by 21 U.S.C. § 823(h)(1). Novelty's failure to maintain effective controls against diversion, including its distribution of large amounts of scheduled listed chemical products that

far exceed legitimate demand, contribute to the illicit manufacture of methamphetamine. The illegal manufacture and abuse of methamphetamine pose a grave threat to public health and safety.

Therefore, it is my preliminary conclusion that Novelty's continued registration during the pendency of these proceedings would constitute an imminent danger to the public health and safety. Pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. 1309.44(a), and the authority granted to me under 28 C.F.R. §§0.100 and 0.104, DEA Certificate of Registration 003563NSY is hereby suspended, effective immediately, with said suspension to remain in effect until a final determination is reached in these proceedings.

Pursuant to 21 U.S.C. § 824(f) and 21 C.F.R. § 1309.44(b), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal and to remove for safekeeping all listed chemicals which Novelty possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Novelty's DEA Certificate of Registration.

THE following procedures are available to Novelty in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Novelty may file with the Deputy Administrator

of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1309.46(d). If Novelty fails to file such a request, the hearing set for March 24, 2008, shall be cancelled in accordance with paragraph 3 below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Novelty may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Novelty's position on the matters of fact and law involved. *See* 21 C.F.R. §1309.53(b).

3. Should Novelty decline to file a request for a hearing or, should it request a hearing and then fail to appear at the designated hearing, Novelty shall be deemed to have waived the hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. *See* 21 C.F.R. §§ 1309.53(c) and (d).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk. Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are

deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45.

/s/ Michele Leonhart
Michele M. Leonhart 1/17/08
Deputy Administrator

cc: Hearing Clerk
Office of Administrative Law Judges

UNITED STATES DEPARTMENT OF JUSTICE

* * *

DRUG ENFORCEMENT ADMINISTRATION

* * *

HEARING

* * *

IN THE MATTER OF:	)	
	)	Docket No. 08-33
NOVELTY DISTRIBUTORS	)	

U.S. Department of Justice
Drug Enforcement Administration
Courtroom E-2123
600 Army Navy Drive
Arlington, VA 22202

Thursday, March 27, 2008

The above entitled matter came on for hearing, pursuant to notice at 9:00 a.m.

BEFORE: GAIL A. RANDALL
Administrative Law Judge

APPEARANCES:

For Novelty Distributors:

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PETER A. ARHANGELSKY, ESQ.
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For the Drug Enforcement Administrations:

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* * *

[1099] Q Now turning our attention to your testimony concerning DMD Pharmaceuticals, now as I understand it from your testimony you discovered in 2002 that a lot number which you give as 02G091H for an ephedrine-containing product was associated with ephedrine that had been found in a Connecticut meth lab. Is that right?

A That's correct.

Q Now – and DEA agents apparently discovered this product in a meth lab in Thompson, Connecticut?

A Yes.

Q Now you've said that you had discussion with a person at DMD who identified that lot number as being associated with an entire lot that had been sold to Novelty?

A Yes.

Q Now did you undertake – I understand – first, let's get a little foundation here. Who was that individual who informed you that the entire lot had been sold to Novelty?

A Dave Riddle.

Q Dave Riddle. And he's an employee [1100] of DMD.

A He's the compliance manager for DMD.

Q All right. Did you ask to see the records establishing that the entire lot had been sent to Novelty?

A No.

Q Did you examine the DMD batch records for the batch that contained the 22 bottles?

A No.

Q Did you examine the DMD shipping records that contained the 22 bottles?

A No.

Q Did you examine the DMD destruction records for the time period the batch that contained the 22 bottles were made?

A No.

Q Did you examine any DMD documents that record loss or theft to determine if any bottles from

the batch that contained the 22 bottles were recorded as lost or stolen?

A No.

Q Did you compare any batch records from DMD to any shipping records from DMD?

[1101] A No.

Q So is it – did you, or to your knowledge, anyone else at DEA establish which retail establishments were sold any of the lot number 02G091H?

A Retail meaning convenience stores?

Q Yes.

A No, DMD does not distribute to retail level stores. They distribute to other DEA registrants who distribute to retail level stores.

Q Did you or to your knowledge anyone else at DEA establish which specific retail establishments that is, convenience stores, sold the 22 bottles?

A No.

Q When you were informed that Novelty – when you informed Novelty of the diversion of the 22 bottles, did you at that point tell Novelty to stop selling SLCs to any stores in Connecticut?

A No.

Q To your knowledge, did anyone else at the DEA advise or recommend that Novelty [1102]

discontinue sales of ephedrine-containing products to any store in Connecticut?

A Not that I'm aware of.

Q Did you inform Novelty that it needed to change its SLC distribution method at that time?

A We advised there needed to be scrutiny of where the product was going.

Q Did you recommend any change in distribution method at that time?

A Not that I recall.

Q To your knowledge, did anyone else in the DEA recommend a change in Novelty's distribution method?

A Not that I'm aware of.

Q Did you give Novelty a notice of diversion concerning the 22 bottles?

A No.

Q Did anyone else at DEA give Novelty a notice of diversion concerning the 22 bottles?

A No.

Q Have you ever given Novelty a notice of diversion concerning the SLC products that it sells?